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The Accountability of Supranational Administration: The Case of European Union Agencies

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THE ACCOUNTABILITY OF SUPRANATIONAL ADMINISTRATION: THE CASE OF EUROPEAN UNION AGENCIES

JOHANNES SAURER*

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INTRODUCTION

The system of European administration is undergoing a fundamental transformation as a result of the European Union's eastern enlargement, ever-growing political tasks, and the challenges of economic globalization.[1] Traditionally, most administrative tasks were either fulfilled directly on the federal level by the European Commission, or by national authorities acting according to the principle of "indirect administration."[2] By the end of the 1980s only two agencies existed.[3] It was only in recent years that an ever increasing number of administrative agencies appeared on the European scale. Many more agencies were founded since 1990, and cover a broad range of policies including environmental law, health care, railway & aviation safety and anti-terrorism issues.[4] The headquarters of these agencies are located all over Europe in cities

1. *See EU Welcomes Romania and Bulgaria*, BBC NEWS, Jan. 1, 2007, http://news.bbc.co.uk/2/hi/europe/6222673.stm (reporting that the entry of Romania and Bulgaria on January 1, 2007 brought the total number of the European Union members to twenty-seven, and the total population to half a billion citizens).

2. *See* Renaud Dehousse, *Misfits: EU Law and the Transformation of European Governance*, *in* GOOD GOVERNANCE IN EUROPE'S INTEGRATED MARKET 207, 221 (Christian Joerges & Renaud Dehousse eds., 2002) (observing that the implementation powers transferred to newly created agencies were usually taken away from national administrations).

3. *See* PAUL CRAIG, EU ADMINISTRATIVE LAW 148-50 (2006) (detailing the history of the creation of E.U. agencies).

4. *See Communication from the Commission to the European Parliament and the Council: European Agencies – The Way Forward*, at 4, COM (2008) 135 final (Mar. 11, 2008) [hereinafter *The Way Forward*] (explaining that the growth in regulatory agencies in the 1990s resulted from "the deepening of the internal market," which required more union-wide regulation).

such as Thessaloniki (Greece), Warsaw (Poland), Lisbon (Portugal) and Copenhagen (Denmark). The accountability of the new regulatory structure on the European scale is often called into question with regard to the availability of judicial review, and political and financial controls.[5] These questions arise both because of the mere novelty of the agency concept and the lack of textual roots in the constitutional framework[6] of the European Union Treaty (TEU) and the European Community Treaty (TEC).[7] Other than more traditional European institutions—such as the Council of Ministers, the Commission and the European Parliament—the E.U. agencies emerged completely outside the Treaty framework. Moreover, the lack of a constitutional framework causes a broad diversification of accountability patterns of E.U. agencies.[8] In addition, the agency-centered American model of the regulatory and administrative state visibly inspired the setting up of E.U. agencies, but the concept of independent administrative agencies developed very differently in the European context.[9] As such, one of the most

5. *See id.* at 5 (discussing the growth in number of E.U. agencies and the resulting issue of "the need for clear lines of accountability to govern agencies' actions").

6. *See, e.g.,* Case 294/83, Parti ecologiste 'Les Verts' v. Parliament, 1986 E.C.R. 1339, ¶ 23 (referring to the European treaties as the Community's "constitutional charter").

7. *See* DEIDRE CURTIN, MIND THE GAP: THE EVOLVING EU EXECUTIVE AND THE CONSTITUTION 7 (Wouter Devroe & Dimitri Droshout eds., 2004) (noting the lack of "constitutionalization" of administrative agencies in the Treaty Establishing a Constitution for Europe); ANTHONY ARNULL ET AL., WYATT & DASHWOOD'S EUROPEAN UNION LAW 10-11 (5th ed. 2006) (listing institutions established by the two founding treaties).

8. *See* Martin Shapiro, *Two Transformations in Administrative Law: American and European?*, *in* THE EUROPEANISATION OF ADMINISTRATIVE LAW: TRANSFORMING NATIONAL DECISION-MAKING PROCEDURES 14, 20-21 (Karl-Heinz Ladeur ed., 2002) (showing how the lack of unified administration of EU regulations results in inconsistencies when the regulations are implemented by national authorities).

9. *See id.* at 21 (discussing the American influence on E.U. administrative law in pushing E.U. courts towards transparency and participation, but in a less radical form); Mark Thatcher, *The Third Force? Independent Regulatory Agencies and Elected Politicians in Europe*, 18 GOVERNANCE 347, 347-49 (2007) (using principal-agent theories, largely developed in the United States, to analyze European agencies); Mark A. Pollack, *Learning from the Americanists (Again): Theory and Method in the Study of Delegation*, 25 W. EUR. POL. 200, 200 (2002) (asserting that European scholars have largely modeled their theories about delegation of powers to non-majoritarian institutions on American theories).

distinctive features within a broad and diverse set of mechanisms is the integration of European national authorities into the federal administrative sphere.

Part I of this Article addresses the developing institutional framework of the E.U. administrative sphere, especially the emergence and structural effects of agency-administration. Part II examines the diversity and unity of various accountability mechanisms in detail by exploring into the institutional design of two particular agencies—the European Medicines Agency, and the European Aviation Safety Agency. Next, Part III draws on future prospects such as the potential constitutionalization of E.U. agencies through the 2007 E.U. Treaty of Lisbon and the emergence of global licensing cooperation.

I. EUROPEAN ADMINISTRATION THROUGH AGENCIES

Today's system of integrated network administration through E.U. agencies developed gradually. With the broad establishment of agencies, the E.U. departed little by little from the institutional paradigms of direct administration on the European and indirect administration on the national level, which had governed European integration since the 1950s.

A. THE TRADITIONAL MODES OF DIRECT AND INDIRECT ADMINISTRATION

The traditional model, which prevailed between the 1950s and 1980s, applied two modes of European administration. In particular, the model provides for direct administration through the Commission, and indirect administration through the Member States.[10] Direct administration through the European Commission is clearly the less frequent administrative mode, which is applied, for example, in the area of competition law and state subsidies, e.g.,

10. *See* Sabino Cassese, *European Administrative Proceedings*, 68 L. & CONTEMP. PROBS. 21, 21 (2004) (discussing the initial model where only competition law and state subsidies were administered by the European Community, while Member States implemented the remaining regulations).

agricultural subsidies.[11] The European institutional architecture is notorious for its idiosyncrasy and complexity. The central European institutions are (1) the E.U. Council—which is comprised of one minister of each Member State, (2) the European Commission, (3) the European Parliament and (4) the European Court of Justice. The legislative power is primarily vested within the Council. The European Parliament has to approve the legislation, of which the two main types are regulations and directives. The Commission does not only issue proposals for E.U. legislation, but is also the institution with the strongest administrative features.[12] Member states entrusted the Commission with adjudicatory functions from the very beginning of European integration in the 1950s.[13] From then onward the Commission also exercised rule-making powers delegated from the Council. Thus the E.U. Council and the European Commission do not only operate in a policy relation ("the Commission proposes, the Council disposes"), but also in a delegation relation.[14] The European Court of Justice acknowledged the necessity of delegated legislation

11. *See* Francesca Bignami, *Foreword: The Administrative Law of the European Union*, 68 L. & CONTEMP. PROBS. 1, 3-4 (2004) (discussing the effect of the European Commission's early use of committees of national regulators to make constant adjustments of quotas and pricing for agricultural subsidies on the development of European administrative law); CRAIG, *supra* note 3, at 31-33 (examining the reasons for the Commission's recent trend to undertake administration more directly, without a systematic relationship with national bureaucracies).

12. *See generally* George A. Bermann, *Executive Power in the New European Constitution*, 3 INT'L J. CONST. L. 440 (2005) (distinguishing administrative and executive authority of the Commission, the Council of Ministers, and the European Council and noting that the Commission's mission is most "executive-branch-sounding").

13. *See* European Commission, The European Commission at Work, Basic Facts, http://ec.europa.eu/atwork/basicfacts/index_en.htm (last visited Oct. 12, 2008) (stating the "European Commission was created to represent the European interest common to all Member States of the Union" and explaining the Commission's role as "guardian of the Treaties and defender of the general interest").

14. *See* Case C-240/90, F.R.G. v. Comm'n, 1992 E.C.R. I-5383, ¶ 41 (holding that the Council may delegate implementation of its regulations to the Commission without providing detailed instructions on the implementation); Anand Menon & Stephen Weatherill, *Legitimacy, Accountability, and Delegation in the European Union*, *in* ACCOUNTABILITY AND LEGITIMACY IN THE EUROPEAN UNION 113, 120 (Anthony Arnull & Daniel Wincott eds., 2002) (focusing on the relationship between delegation and legitimacy in the legislative framework).

early on, in the 1958 *Meroni* case, however also set relatively strict limits for such delegations.[15]

In *Meroni*, the High Authority of the European Coal and Steel Community (ECSC) had created a special obligatory system to regulate the ferrous scrap market. This equalization system was to be administered by Brussels based agencies "under the responsibility of the High Authority."[16] The case came to the ECJ after the Italian Steel Company Meroni refused to pay a fee to the Imported Ferrous Scrap Equalization Fund.[17] The ECJ acknowledged the general possibility of transferring power, but simultaneously limited the discretion of the E.U. legislature to delegate that power. The Court stated first that a delegating authority "could not confer upon the authority receiving the delegation powers different from those which the delegating authority itself received under the Treaty"[18] and second that it is not possible to delegate power involving a wide margin of discretion.[19] The "execution of actual economic policy" should be unlawful, since the latter "replaces the choices of the delegator by the choices of the delegate" and "brings about an actual transfer of responsibility."[20]

More than fifty years after its establishment, the *Meroni* doctrine is called into question by the partially extensive practice of delegation to both the Commission and further European institutions, such as the European Central Bank,[21] and the regulatory agencies.[22]

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15. Case 10/56, Meroni & Co., Industrie Metallurgiche, SpA, v. High Auth. of the European Coal & Steel Cmty., 1958 E.C.R. 53.

16. *Id*. at 169.

17. *See id.* at 160 (observing that the Italian company filed for an annulment of the High Authority's demand of payment to the Imported Ferrous Scrap Equalization Fund).

18. *Id*. at 171.

19. *See id*. at 173 (reasoning that delegating wide discretionary powers to bodies that were not established by the Treaty is to subvert the Treaty's guarantee of the balance of powers).

20. *Id*. at 173.

21. *See* Rosa Maria Lastra, *The Division of Responsibilities Between the European Central Bank and the National Central Bank Within the European System of Central Banks*, 6 COLUM. J. EUR. L. 167, 167, 180 (2000) (arguing that the responsibilities of the European Central Bank and the national central banks "have not been clearly transferred from the national to the supranational arena" and "the language of the treaties allows for various interpretations" of the autonomy of the European Central Bank). *But see* Roger J. Goebel, *Court of Justice Oversight*

In particular, the emergence of a system of increasingly powerful E.U. agencies challenges the basic idea of *Meroni*, which requires justification for every administrative action implying policy choices.[23] However, the European Court of Justice apparently still considers the *Meroni* doctrine good law. In 2005, the ECJ explicitly referred to *Meroni* in a case concerning the delegation of implementing powers from the Council to the Commission, noting that "when the Community legislature wishes to delegate its power to amend aspects of the legislative act at issue, it must ensure that that power is clearly defined and that the exercise of the power is subject to strict review in the light of objective criteria."[24] Similarly, the ECJ stressed the ongoing importance of *Meroni* in another 2005 case concerning rules on staff management issued by the European Central Bank.[25] The European Commission also adheres to the

Over the European Central Bank, 29 FORDHAM INT'L L.J. 610, 628-32 (2006) (discussing the Commission v. European Central Bank, Case C-11/00, 2003 E.C.R. I-7147, opinion by the European Court of Justice ("ECJ") in which the court upheld the Commission's power to delegate its antifraud powers to an agency and grant it independence even from the Commission itself).

22. *See* Edoardo Chiti, *Beyond Meroni: The Community Legitimacy of the Provisions Establishing the European Agencies*, *in* EUROPEAN REGULATORY AGENCIES 75, 80 (Giacinto Della Cananea ed., 2004) (asserting that "the setting up of Community bodies provided with legal personality does not seem to imply a hypothesis of delegation of powers by the Commission to an outside body in the same sense as in the *Meroni* jurisprudence").

23. *See* Herwig C.H. Hofmann & Alexander H. Türk, *Policy Implementation*, *in* EU ADMINISTRATIVE GOVERNANCE 74, 86 (Herwig C.H. Hofmann & Alexander H. Türk eds., 2006); *see also* Stefan Griller & Andreas Orator, *Meroni Revisited – Empowering European Agencies Between Efficiency and Legitimacy* 1, 6 (New Gov: New Modes of Governance Project, Reference No. 04/D40, 2007), www.eu-newgov.org/database/DELIV/D04D40_WP_Meroni_Revisited.pdf (assessing the continuing validity of the Meroni doctrine despite later case law that "clearly shows that these constraints to the transposability do not exist").

24. *See* Joined Cases C-154/04 & C-155/04, The Queen v. Sec'y of State for Health, 2005 E.C.R. I-6451, ¶ 90 (explaining that delegation standards should be relied on to prevent the EU Council from conferring on the delegate "a discretion which, in the case of legislation concerning the functioning of the internal market in goods, would be capable of impeding, excessively and without transparency, the free movement of the goods in question").

25. *See* Case C-301/02, Tralli v. European Cent. Bank, 2005 ECR I-4071, ¶¶ 41-46 (finding the European Central Bank's delegation of power in conformity with the *Meroni* principles); *see also* Deirdre Curtin, *Holding (Quasi-) Autonomous EU Administrative Actors to Public Account*, 13 EUR. L.J. 523, 528 (2007) (synthesizing the 2005 ECJ case *Tralli* as allowing delegations of power that confer authority to make technical decisions without broad economic or

Meroni doctrine, declaring that under current E.U. law, "there are clear and strict limits to the autonomous power of regulatory agencies."[26]

Interestingly the Commission has remained a scarcely staffed body with currently about 25,000 employees.[27] This is a remarkably small figure compared to the U.S. federal government, which currently employs 1.8 Million civilians.[28] Against the backdrop of twenty-seven E.U. Member States, nearly 500 Million E.U. citizens, twenty-three official languages and ever-increasing political tasks, the puzzling question is how European administration works with so few administrators. The classical answer was the concept of "indirect administration." The national authorities acted simultaneously as agents for both domestic and European policy implementation.[29] It was only over time that more and more tasks were directly assigned to actors on the federal European level—and particularly actors beyond the Commission. As the European integration became ever closer,[30] the scope of tasks to be fulfilled on the E.U. level enlarged tremendously, both in terms of regulation and adjudication.[31] The national administrations were increasingly overarched by European

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political consequences).

26. *See The Way Forward*, *supra* note 4, at 5 (stating further that "[a]gencies cannot be given the power to adopt general regulatory measures. They are limited to taking individual decisions . . . without genuine discretionary power").

27. *See* European Commission, Civil Service, Staff Figures, http://ec.europa.eu/civil_service/about/figures/index_en.htm (last visited Oct. 12, 2008) (reporting the total number of Commission staff at about 24,500 officials and temporary agents, with approximately an additional 9,500 external staff members). *But see* Rob Watts, *Found: the EU's 20,000 Employees Hiding in Brussels*, THE SUNDAY TELEGRAPH (London), Jan. 28, 2007, at 15 (suggesting that the count for European Commission employees is actually higher than the 25,000 staff it claims on its website).

28. U.S. DEPARTMENT OF LABOR, BUREAU OF LABOR AND STATISTICS, CAREER GUIDE TO INDUSTRIES, FEDERAL GOVERNMENT, EXCLUDING THE POSTAL SERVICE (2008-09 ed.), http://www.bls.gov/oco/cg/cgs041.htm.

29. *See* Cassese, *supra* note 10, at 21 (citing the "allocation of European social and agricultural funds" as an example where national administrations were in charge of implementing Community policies).

30. *See* ARNULL ET AL., *supra* note 7, at 16-18 (emphasizing the importance of the European Single Act of 1986 and the Treaty on the European Union in strengthening the economic and political cooperation among member states).

31. *See id.* at 113 (pointing out the tremendous growth in the European Community's competencies in the scope of activities).

structures.[32] One issue was contracting out to private parties, which began to play a larger role in the 1980s and 1990s. Contracts were used to guarantee for the delivery of many of the programs directly administered by the Commission, for example in the context of promotion for tourism in the European Community, of decentralized cooperation with non-member countries of the southern Mediterranean, and of the European Community Humanitarian Office (ECHO).[33] However, in the late 1990s, these contracting procedures were heavily criticized for their lack of transparency and financial opaqueness.[34] There were several critical investigations by a Committee of Independent Experts,[35] and also by the European Court of Auditors,[36] which finally resulted in the resignation of European Commission President Jacques Santer.[37]

Another important development was the emergence of the so-called Comitology system[38] that incorporated the rule-making

32. *See* Herwig C. H. Hofmann & Alexander Türk, *The Department of Integrated Administration in the EU and its Consequences*, 13 EUR. L.J. 253, 254 (2007) (illustrating how the traditional distinction between administrative roles of Member States and E.U. actors "has become increasingly blurred" and has resulted in Europe's "integrated administration"); Cassese, *supra* note 10, at 35 (remarking on the hierarchical superiority of the European supranational institutions over national ones).

33. *See* CRAIG, *supra* note 3, at 6-7, 52-53 (detailing the Commission's contracting practices and some resultant problems).

34. *See id.* at 3-4 (discussing the long-running concern about allegations of fraud and mismanagement in the European Community's contracting practices).

35. *See Committee of Independent Experts First Report on Allegations Regarding Fraud, Mismanagement, and Nepotism in the European Commission* 137-39 (Mar. 1999), *available at* http://www.europarl.europa.eu/experts/report1_en.htm (examining cases of fraud, mismanagement, and nepotism in the Tourism Unit, MED programme, ECHO, Technical Assistance Office, Security Office, and Nuclear Safety).

36. *See Court of Auditors Special Report No 16/2000 on Tendering Procedures for Service Contracts Under the Phare and Tacis Programmes, Together with the Commission's Replies*, 2000 O.J. (C 350) 1, 3 (noting that the Auditors conducted an investigation of certain programs in response to a request made by the person in charge of closing out financial year 1997).

37. *See* CRAIG, *supra* note 3, at 52 (attributing the demise of the Santer Commission to revelations about fraud surrounding Commission contracts).

38. *See* Guenther A. Schaefer & Alexander Türk, *The Role of Implementing Committees*, *in* THE ROLE OF COMMITTEES IN THE POLICY-PROCESS OF THE EUROPEAN UNION 182, 182-83 (Thomas Christiansen & Torbjörn Larsson eds., 2007) (providing an overview of factors leading up to the development of the comitology system in which the Commission must consult committees composed

powers of the European Commission gradually into a system currently encompassing between 200 and 300 different committees of various competences.[39] From the 1960s on, ever more Committees emerged, which were comprised of Member State nominees, and chaired by a Commission official.[40] Before adopting an implementing rule, the Commission has to present a draft for evaluation and comment to the specific committee, sometimes even requiring the committee's approval.[41] The Comitology system was conceived of very differently in the academia and in the general public. Although some scholars were very sympathetic, and stressed the deliberative and democratic potential,[42] the majority of scholars and the general public were suspicious of the informality and lack of transparency in the system.[43] Over time the Comitology regime was

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of representatives of the Member States before implementing legislation that was delegated to it by the Council).

39. *See Report from the Commission on the Working of Committees During 2005*, 10, COM (2006) 466 final (Sept. 8, 2006) (reporting that there were 250 comitology committees in 2005).

40. *See* Jens Blom-Hensen, *The Origins of the EU Comitology System: A Case of Informal Agenda-Setting by the Commission*, 15 EUR. PUB. POL'Y 208, 209 (2008) (arguing that the development of the comitology system began in the early 1960s as a way to address issues in regulating agriculture among the Member States). *See also* Ellen Vos, *EU Committees: The Evolution of Unforeseen Institutional Actors in European Product Regulation*, *in* EU COMMUNITIES: SOCIAL REGULATION, LAW AND POLITICS 19, 24 (Christian Joerges & Ellen Vos eds., 1999) (explaining that advisory and management committees are composed of "representatives of Member States and chaired by a representative of the Commission").

41. *See* Vos, *supra* note 40, at 20-21 (observing the Council's practice of creating two types of committees: those whose approval was required in order for the Commission's decisions to become effective and those whose function was purely advisory).

42. *See* Oliver Gerstenberg & Charles F. Sabel, *Directly-Deliberative Polyarchy: An Institutional Ideal for Europe?*, *in* GOOD GOVERNANCE IN EUROPE'S INTEGRATED MARKET 289, 295 (Christian Joerges & Renaud Dehousse eds., 2002) (characterizing comitology as "deliberative supranationalism," in which a group of independent experts make carefully weighted decisions that benefit the entire European Community); Christian Joerges & Jurgen Neyer, *Transforming Strategic Interaction into Deliberative Problem-Solving: European Comitology in the Foodstuffs Sector*, 4 J. EUR. PUB. POL'Y 609, 620-21 (1997) (arguing that the comitology system has promoted a " culture of inter-administrative partnership which relies on persuasion, argument and discursive processes").

43. *See* Renaud Dehousse, *Comitology: Who Watches the Watchmen?*, 10 J. EUR. PUB. POL'Y 798, 803 (2003) (suggesting a possibility of resentment toward

partially unified and institutionalized. The First Comitology Decision of the Council of 1987 included a reduction of the basic committee procedures (reducing to three: advisory, management, and regulatory) and also provided for safeguard committee procedures.[44] The Second Comitology Decision of 1999 granted public access to a certain extent, and also involved the European Parliament more intensively into the rulemaking process.[45] In the 2000s, there have again been several attempts for further enhancement of transparency and participation features.[46]

B. EMERGENCE AND INSTITUTIONALIZATION OF E.U. AGENCIES

From the preceding section it has become clear that the classical administrative pattern of administrative organization—characterized by (few) administrative tasks carried out directly on the European level by the Commission, and the bulk of tasks according to the paradigm of "indirect organization" carried out by the Member States—had reached its capacity limits when the E.U. took on an ever-increasing number of new political tasks.[47] Quantitatively, the number of E.U. agencies rose rapidly from two entities before 1990 to now approximately twenty-five. Qualitatively, the E.U. agencies

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committees of experts meeting behind closed doors to decide matters of public interest). *See also* Joseph Weiler, *Prologue: Amsterdam and the Quest for Constitutional Democracy*, *in* LEGAL ISSUES OF AMSTERDAM TREATY 1, 12 (David O'Keeffe & Patrick Twomey eds., 1999) (asserting that "the reality of '*comitology*' displays a beast which is quite different from the formal description" because its rules of informality in the decision making processes do not reflect national interests, but instead perpetuate "functional deliberation and sectoral pressure").

44. *See* Council Decision 87/373, 1987 O.J. (L 197) 33 (EC); *see also* CRAIG, *supra* note 3, at 106-07 (characterizing the reduction of committee procedures to three functions as "an improvement on the status quo ante").

45. Council Decision 468, 1999 O.J. (L 184) 23, 23-24 (EC).

46. *See* Schaefer & Türk, *supra* note 38, at 185 (discussing the 2006 Council Decision that gives both the Council and the European Parliament "extensive rights of control over implementing acts which affect both institutions as co-legislators); CRAIG, *supra* note 3, at 111-12 (noting that in 2002, the Commission proposed to amend the Council's Second Comitology Decision).

47. *See* R. Daniel Kelemen, *The Politics of Eurocracy: Building a New European State?*, *in* 7 THE STATE OF THE EUROPEAN UNION 173, 181, 185 (Nicolas Jabko & Craig Parsons eds., 2005) (reporting that the 1990s wave of agency creation was prompted by functional pressures on the Commission resulting from the single market initiative and noting that such pressures continue to grow).

became increasingly powerful by taking on advisory tasks of a formal nature, with tremendous de facto influence in the 1990s, and formal licensing powers in the 2000s.

1. A Generation Model of E.U. Agencies

Today's system of integrated network administration, including E.U. agencies, came only gradually into existence. It was not until 1975 that a first, rather reluctant, step towards the establishment of agencies on the European level was taken. In that year, the European Centre for the Development of Vocational Training (Cedefop) and the European Foundation for the Improvement of Living and Working Conditions (Eurofound) were established.[48] These institutions were intended to fulfill communication and social dialogue tasks.[49] At the time of their founding, the involved parties were aware of the limited institutional strength and importance of Cedefop and Eurofound, and they were not intended to be part of a larger process of institutionalization. For this reason, these first agencies could only be retrospectively referred to as "first generation agencies." Interestingly, in the 1980s many new agencies were established at European national levels, in various , particularly in the area of market competition regulation, including general competition authorities, and utility and financial regulators.[50]

In the early 1990s the E.U. established a second generation of agencies. This time the institutional design followed the idea of creating distinctive entities at the European level, particularly to unburden the existing European administration.[51] Yet the influence of the *Meroni* doctrine and its opposition towards discretionary European administrative bodies was still very strong.[52] Thus, the

48. Council Regulation 337/75, art. 1, 1975 O.J. (L 39) 1 (EC); Council Regulation 1365/75, art. 1, 1975 O.J. (L 139) 1 (EC).

49. Hofmann & Türk, *supra* note 23, at 86.

50. *See* Giandomenico Majone, *The Rise of the Regulatory State in Europe*, 29 W. EUR. POL. 77, 83-84 (1994) (listing agencies created in France and Great Britain in the 1970s-1980s and noting that all other European countries experienced similar developments).

51. *See* CRAIG, *supra* note 3, at 146 (noting that the agencies would allow the Commission to concentrate on its "core function of policy formulation, with the agencies implementing this policy in specific technical areas").

52. *See* Dehousse, *supra* note 2, at 218-20 (attributing the Commission's reluctance to delegate to two factors: the *Meroni* doctrine and the fear of creating

agencies remained focused on advisory tasks and preliminary work for Commission and Council, which issued all formal decisions.[53] For example, the admission of a new pharmaceutical to the market is only prepared by the European Medicines Agency, but is always formally adopted by the Commission.[54] The agencies created in the 1990s were given tasks of technical or scientific natures, and charged with completing the internal market. Equally new was the decentralizing effect that came along with the European Council's decision to disseminate the agency headquarters throughout Europe.[55] Contextually, in the late 1980s and early 1990s various circumstances caused the Member States to support further European integration and a new step of institutionalization. There are three major aspects to this. First, with the European Single Act of 1986, European integration had taken one of its historically most important steps. The European Single Act opened up several new political tasks, especially in fulfilling the European Common Market.[56] Second, there was growing unwillingness among Member States to hand over power to the Commission, which might have caused the Commission to favor "independent" agencies and transnational regulatory networks.[57] Third, the model of U.S. independent agencies was closely studied,[58] and increasingly found supporters among E.U.

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rival institutions that will encroach on the Commission's power).

53. *See id.* at 219 (commenting on the history of interpreting agencies' powers narrowly).

54. *See infra* Part II.A.1 (detailing a case study into the accountability features of the European Medicines Agency (EMEA)).

55. *See* Council Directive 323/1, art. 1, 1993 O.J. (C 323) 1 (listing locations for new agencies); Ellen Vos, *Agencies and the European Union*, *in* AGENCIES IN EUROPEAN AND COMPARATIVE PERSPECTIVE 113, 126 (Tom Zwart & Luc Verhey eds., 2003) (detailing the debates surrounding locations of the second-generation agencies).

56. *See* Peter Holmes, *Non-Tariff Barriers*, *in* THE ECONOMICS OF THE SINGLE EUROPEAN ACT 27, 29-30 (George McKenzie & Anthony J. Venables eds., 1991) (observing that, in addition to setting a deadline for the creation of an internal market, the Single European Act granted the Council of Ministers powers to harmonize national laws).

57. *See* Dehousse, *supra* note 2, at 217 (commenting on the growing gap between the ever-increasing need for the regulation of risk on the E.U. level and the relatively constant number of the Commission staff over the years).

58. JOACHIM SPALCKE, ARZNEIMITTELZULASSUNGSVERFAHREN IN DER EUROPÄISCHEN UNION UND DEN VEREINIGTEN STAATEN VON AMERIKA: ENTWICKLUNG UND HARMONISIERUNG (2004).

law makers.[59] The legal basis for this wave of agency founding was the then-Article 235 (now Article 308) of the Treaty of the European Community.[60] In 1990, the European Environment Agency (EEA) successfully launched, mostly as an information-managing institution.[61] A number of further agencies immediately followed, including the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA, 1993), the Office for Harmonization in the Internal Market (OHIM, 1993), the European Agency for Health and Safety at Work (EU-OSHA, 1994) and the Community Plant Variety Office (CPVO, 1994).[62] One of the most significant new agencies of this area was the European Agency for the Evaluation of Medicinal Products (EMEA, 1993).[63] To ensure the support of the Member States, the E.U. arranged the new agencies as part of a "hub and spoke network," which guaranteed an ongoing role for the Member States.[64] This idea of cooperation (also realized in the management boards comprised of Member State representatives) actually made the agencies, from the national perspective, appear much less as an

59. *See* Xenophon A. Yataganas, *Delegation of Regulatory Authority in the European Union: The Relevance of the American Model of Independent Agencies* 23-27 (The Jean Monnet Program, Working Paper 3/01, 2001), http://www.jeanmonnetprogram.org/papers/01/010301.html (explaining the expansion of U.S. style independent regulatory authority as a response to social and economic changes in the E.U.); Giandomenico Majone, *From the Positive to the Regulatory State: Causes and Consequence of Changes in the Mode of Governance*, 17 J. PUB. POL'Y 139, 152-56 (1997) (comparing the rise of the European regulatory state to the U.S. system of agencies and judicial review).

60. *See* CRAIG, *supra* note 3, at 150 (noting that Article 308 is now used only for agencies tasked with implementing policy based on that Article).

61. Council Regulation 1210/90, art. 1, 1990 O.J. (L 120) (EC).

62. *See* Yataganas, *supra* note 59, at n.107 (listing dates of establishment of European agencies).

63. *See* European Medicines Agency, About EMEA – Structure, http://www.emea.europa.eu/htms/aboutus/emeaoverview.htm (summarizing EMEA's mission as "protection and promotion of public and animal health" by conducting scientific evaluations of applications for marketing of new medicines).

64. *See* Kelemen, *supra* note 47, at 181 (noting that the network model, in which "the European agencies would serve as hubs of regulatory networks with the national authorities their spokes," helped alleviate tensions between supranational and national authorities). *See also* Pierre Larouche, *Coordination of European and Member State Regulatory Policy: Horizontal, Vertical and Transversal Aspects*, *in* REGULATION THROUGH AGENCIES IN THE EU: A NEW PARADIGM OF EUROPEAN GOVERNANCE 164 (Damien Geradin et al. eds., 2005) (using competition law as an example of vertical, horizontal, and transversal coordination systems between and among European regulatory agencies and member states).

evil, particularly since there were similarities to the received Comitology system.

The institutional design of the third agency generation in the 2000s was even stronger. The new agencies included the European Network and Information Security Agency (ENISA, 2004), the European Centre for Disease Prevention and Control (ECDC, 2004), the European Aviation Safety Agency (EASA, 2002), the European Railway Agency (ERA, 2004) and the Community Fishery Control Agency (CFCA, 2005).[65] Among the new entities were the first E.U. agencies with formal licensing power and competences to investigate the enforcement of national laws. In particular, these entities are the European Aviation Safety Agency, which is issuing type-certificates for aircrafts,[66] and the European Chemicals Agency, that the E.U. designed to ensure the technical, scientific and administrative progress of the chemical regulation regime established by the 2006 REACH regulation.[67] With this qualitative extension of powers, the legal constraints of the *Meroni* doctrine seemingly declined.[68] According to a recent statement of the European Commission, the agencies established under the EC treaty altogether "employ some 3,800 staff, with an annual budget of around 1,100 million Euro, including a Community contribution of around 559 million."[69]

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65. *See generally* Parliament & Council Regulation 460/2004, 2004 O.J. (L 77) 1 (EC) (creating the European Network and Information Security Agency); Parliament & Council Regulation 851/2004, 2004 O.J. (L 142) 1 (EC) (creating the European Centre for Disease Prevention and Control); Parliament & Council Regulation 1592/2002, 2002 O.J. (L 240) 1 (EC) (repealed Apr. 8, 2008) (creating the European Aviation and Safety Agency); Parliament & Council Regulation 881/2004, 2004 O.J. (L 164) 1 (EC) (creating the European Railway Agency); Council Regulation 768/2005, 2005 O.J. (L 128) 1 (EC) (creating the Community Fishery Control Agency).

66. Parliament & Council Regulation 216/2008, arts. 18-21, 2008 O.J. (L 79) 1, 14-16 (EC). *See infra* Part III.A.2 (assessing the agency in detail).

67. Parliament & Council Regulation 1907/2006, ¶¶ 15, 19, 20, 24, 29, 33, 2006 O.J. (L 396) 1 (EU) (requiring manufacturers of chemicals to submit reports to the European Chemicals Agency and empowering the agency to require registration of certain substances).

68. *See* Griller & Orator, *supra* note 23, at 6-11 (presenting arguments for overruling *Meroni* as burdensome and inefficient and showing that the ECJ, the Commission, and many commentators all support its continued application).

69. *The Way Forward*, *supra* note 4, at 4.

2. The Rationale for E.U. Agencies in the 2000s: Eastern Enlargement, New Governance, Institutional Credibility

The latest and probably most significant wave of agency establishment occurred for three major reasons. First, the enormous dimensions of the next round of E.U. enlargement became visible. It turned out that by 2004 the European Union would have expanded from fifteen to twenty-five Member States, adding to the Union such states as Poland, the Czech Republic and Hungary.[70] Even further enlargement came in sight, potentially extending the E.U. to include Bulgaria and Romania (realized in 2007), Turkey, and the successor states of the former Yugoslavia (Slovenia joined the E.U. in 2004).[71] With the significantly increased workload and variety of new tasks resulting from the enlargement, there was an obvious need for the creation of new European administrative bodies, particularly to unburden the European Commission. The agency model was proposed as a work relief for the existing E.U. institutions.[72] Relying on agencies to implement policies in specific technical areas would allow the Commission to focus on the function of forming the policies. With regard to the composition of the agencies, the Commission favored supranational regulators over nationally controlled bodies.[73]

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70. Carol Cosgrove-Sacks, *Challenges of Adjustment: Economic Integration in a Wider Europe*, *in* ADJUSTING TO EU ENLARGEMENT: RECURRING ISSUES IN A NEW SETTING 151, 151 (Constantine A. Stephanou ed., 2006) (remarking on the dramatic changes of the geopolitical and economic framework in Europe with the entry of the Eastern European states into the EU).

71. *See generally* ADJUSTING TO EU ENLARGEMENT: RECURRING ISSUES IN A NEW SETTING, *supra* note 70 (providing an overview of institutional consequences of the eastern enlargement).

72. *See Budget Directorate General Evaluation Unit*, *Meta-Evaluation on the Community Agency System* 28-31 (Sept. 2003), http://ec.europa.eu/budget/library/documents/evaluation/eval_review/meta_eval_agencies_en.pdf [hereinafter *Meta-Evaluation on the Community Agency System*] (exploring the impact of the "rationale of outsourcing" on the efficiency and effectiveness of existing agencies by discussing previously unmet needs and potential value added); ÉLARGISSEMENT: COMMENT L'EUROPE S'ADAPTE (Renaud Dehousse et al. eds., 2006).

73. *See Meta-Evaluation on the Community Agency System*, *supra* note 72, at 6-7 (enhancing the role and representation of the Commission on the Agencies' Boards).

Second, a general shift in administrative policies, which is often labeled "from government to governance" occurred almost simultaneously on the national and federal level of European politics.[74] The E.U. developed and established new models of public governance, often applying microeconomic models to public institutions.[75] One of the most persuasive ideas in this context was the loosening of former hierarchical bureaucratic models.[76] Europe increasingly recognized that the top-down approach of command and control administration was an inadequate regulatory technique for increasingly flexible and globalized industries.[77] Throughout Europe regulatory agencies were often established as regulatory authorities in privatized markets, which had formerly been part of the public infrastructure.[78]

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74. *See* David Bach & Abraham L. Newman, *The European Regulatory State and Global Public Policy: Micro-Institutions, Macro-Influence*, 14 J. EUR. PUB. POL'Y 827, 827-28, 830 (2007) (arguing that growth in market competition facilitated the domestic shift to governance making coordination between those institutions necessary on a European level); Jens-Peter Schneider, *Regulation and Europeanisation as Key Patterns of Change in Administrative Law*, *in* THE TRANSFORMATION OF ADMINISTRATIVE LAW IN EUROPE 309, 317-18 (Matthias Ruffert ed., 2007) (commenting on the development of mutual trust among Member States that eliminates the need for detailed harmonization of administrative procedures); Christoph Möllers, European Governance: Meaning and Value of a Concept, 43 COMMON MKT. L. REV. 313 (2006).

75. *See* Paul Magnette, *The Politics of Regulation in the European Union*, *in* REGULATION THROUGH AGENCIES IN THE EU: A NEW PARADIGM OF EUROPEAN GOVERNANCE 4-5 (Damien Geradin et al. eds., 2005) (describing the evolution from a post-war Keynesian state towards a regulatory state in which public authorities act based on a cost-benefit analysis).

76. *See* Majone, *supra* note 50, at 79-80, 156 (explaining that the growth of the regulatory state has reduced hierarchy because basic bureaucratic conflicts are externalized and characterizing deregulation and privatization as mechanisms that lead to less burdensome government intervention).

77. *See* Martin Lodge, *The Europeanisation of Governance – Top Down, Bottom Up or Both?*, *in* THE EUROPEANISATION OF GOVERNANCE 59, 67-71 (Gunnar Folke Schuppert ed., 2006) (arguing that Europeanisation is inherently a combination of top-down and bottom-up regulation because of the relationship between the European government and the individual state governments).

78. *See* Thatcher, *supra* note 9, at 352-54 (using Germany, France, and Italy to examine the relationship between independent regulatory agencies); Giacinto Della Cananea, *The Regulation of Public Services in Italy*, 68 INT'L REV. OF ADMIN. SCI. 73, 76 (2002) (connecting the history of regulatory agencies in Italy to privatization and liberalization in the country and the evolution of the single European market).

Third, the E.U. was looking for institutional responses to the heavy credibility crisis that struck the European bureaucracy in the mid-1990s. The crisis, which culminated in the Santer-Commission stepping down, grew out of a number of corruption cases, and increasing public suspicion of the opaque structures of the European bureaucracy.[79] In an effort to overcome the crisis, the E.U. institutions undertook serious efforts to regain the trust of the European governments and peoples.[80] Primarily the Commission was concerned with strengthening the accountability features of the E.U. bureaucracy. Recognizing the need for an alternative to the traditional rule-making process that is hampered by its loose and unstable committee structure involving a number of private actors with unclear legitimacy, the Commission's White Paper on European Governance of 2001 proposed the establishment of agencies, stating:

> The creation of further autonomous E.U. regulatory agencies in clearly defined areas will improve the way rules are applied and enforced across the Union. Such agencies should be granted the power to take individual decisions in application of regulatory measures. They should operate with a degree of independence and within a clear framework established by the legislature. The regulation creating each agency should set out the limits of their activities and powers, their responsibilities and requirements for openness.[81]

In 2002 the Commission dealt in a specific Communication with the issue:

> [Agencies] would make the executive more effective at European level in highly specialized technical areas requiring

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79. *See* CAROL HARLOW, ACCOUNTABILITY IN THE EUROPEAN UNION 53-55 (2002) (detailing allegations of fraud and mismanagement leading up to the Saunter scandal); *see also* Veith Mehde, *Responsibility and Accountability in the European Commission*, 40 COMMON MKT. L. REV. 423, 424-26 (2003) (exploring accountability particularly with respect to the impact of resignation of an existing body).

80. Koen Lenaerts & Amaryllis Verhoeven, *Institutional Balance as a Guarantee for Democracy in EU Governance*, *in* GOOD GOVERNANCE IN EUROPE'S INTEGRATED MARKET 35, 61-64 (Christian Joerges & Renaud Dehousse eds., 2002) (discussing the accountability and censure measures put in place following the Santer crisis).

81. *Commission White Paper on European Governance*, at 24, COM (2001) 428 final (July 25, 2001) (emphasis omitted).

> advanced expertise and continuity, credibility and visibility of public action . . . . The main advantage of using the agencies is that their decisions are based on purely technical evaluations of very high quality and are not influenced by political or contingent considerations.[82]

Strengthened and decentralized agencies were seen as a helpful and promising tool to improve regulation.[83] Moreover, the Commission argued for the adoption of a legally formalized agency framework, including rules for the creation of agencies, their procedures, and their supervision.[84] The successful process of institutional bargaining showed support for the strengthened European administrative sphere in the European Parliament.[85] The Commission saw enhanced agency institutionalization as a favorable means to respond to the arguments against growing informal and uncontrolled powers.[86] Yet the Council, given its nature as representative of the Member State governments, pushed strongly to ensure the decisive and enduring influence of those Member States.[87] Thus the Council in particular sought agency control through management boards dominated by Member State representatives, and

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82. *Communication from the Commission, The Operating Framework for the European Regulatory Agencies*, at 5, COM (2002) 718 final (Nov. 12, 2002); *see also Commission White Paper on European Governance*, *supra* note 81, at 24 (discussing the creation of autonomous regulatory agencies and their benefits over traditional processes). "The advantage of agencies is often their ability to draw on highly technical, sectoral know-how, the increased visibility they give for the sectors concerned (and sometimes the public) and the cost-savings that they offer to business. For the Commission, the creation of agencies is also a useful way of ensuring it focuses resources on core tasks." *Id.*

83. Martin Shapiro, *The Problems of Independent Agencies in the United States and the European Union*, 4 J. EUR. PUB. POL'Y 276, 282 (1997) (stating that E.U. agencies have the huge advantage of not being in Brussels and not being the Commission; they aim to be viewed as "Europe-wide epistemic communities . . . whose technical truths transcend politics").

84. *See* Kelemen, *supra* note 47, at 182-83 (explaining that the Commission proposed the framework because the 2001 White Paper recommended creating a formal framework).

85. *See id.* at 179 (using the struggle over the design of management boards as an example of the complex political structure behind the growth of agencies). Distinct from the Commission and Council, the European Parliament demanded more transparency, procedure, and oversight. *Id.*

86. *See id.* at 185 (rationalizing the growing support for agencies as an antidote to the perceived loss of the Commission's independence).

87. *Id.* at 179.

through integration of national regulatory authorities into the operations via a hub-and-spoke model.[88] One could see the influence of the Council's opinion in the modified standpoint found in the Commission's 2005 proposal for an inter-institutional agreement on the operating framework for the European regulatory agencies,[89] which nevertheless failed.[90]

3. The Legal Basis of E.U. Agencies

There is ongoing debate regarding the correct legal procedure used to establish agencies. In the 1970s and 1980s most agencies were based on Art. 308 TEC.[91] This article provides an additional legislative competence for circumstances not explicitly mentioned in the Treaty, and requires a positive vote in the unanimous consultation procedure.[92] An alternative and increasingly popular mode of agency setting applies specific sectoral provisions or Art. 95 TEC, which refers to measures establishing the internal market, and to the qualified majority of the co-decision procedure under Art. 251 TEC.[93] The practical relevance of this discussion is enormous, since in the latter case a few vetos could bar the agency establishment.[94] E.U. officials and legal scholars tended to interpret Art. 95 TEC as a sufficient constitutional basis for creating E.U. agencies, such as in the context of the 2004 regulation reforming the European Medicines

88. *Id.*

89. *Commission*, *Draft Interinstitutional Agreement on the Operating Framework for the European Regulatory Agencies*, at 6-7, COM (2005) 59 final (Feb. 25, 2005) [hereinafter *Draft Interinstitutional Agreement*].

90. *See The Way Forward*, *supra* note 4, at 6 (describing the previous failure to create a common framework for the regulatory agencies).

91. Alexander Kreher, *Agencies in the European Community – A Step Towards Administrative Integration in Europe*, 4 J. EUR. PUB. POL'Y 225 (1997).

92. Treaty Establishing the European Community, art. 308, Nov. 10, 1997, 1997 O.J. (C 340) 3 [hereinafter EC Treaty] (creating the requirements for the Council to act unanimously and take appropriate measures when the Treaty does not provide necessary procedures).

93. *See id.* art. 95(1) (providing for the Council's power to adopt measures creating and maintaining an internal market).

94. *See* George Tsebelis & Xenophon Yataganas, *Veto Players and Decision-making in the EU after Nice: Policy Stability and Bureaucratic/Judicial Discretion*, 40 J. COMMON MKT. STUD. 283, 284-86 (2002) (calculating the new qualified majority requirements under the Treaty of Nice and showing that it would take only Germany, together with one large and one small country, to block any decision in the Council).

Agency.[95] The European Court of Justice most recently dealt with the issue in the *European Network and Information Security* Agency (ENISA) case.[96] In that case, the United Kingdom had challenged the legality of ENISA, which the E.U. established in Regulation (EC) No. 460/2004, based on Article 95 TEC.[97] The United Kingdom's main argument had been that the ENISA-Regulation lacked the thematic connection to the establishment and functioning of the internal market, as required in the provision.[98] The European Court of Justice dismissed the action, and found that the regulation framing ENISA was rightly based on Article 95 TEC.[99] Accordingly the European Commission based its most recent initiative for a European agency to regulate the European telecommunication market on Article 95 TEC.[100]

An additional track of E.U. administration building that recently opened is the establishment of the so-called "executive agencies." Despite the terminological similarity, these entities are very distinct from the E.U. agencies, and are rooted in a 2002 Regulation.[101] Acting on a minor level of supranational governance, they do not depend upon a legislative foundation through E.U. Council and European Parliament, but are set up directly by the European Commission. The existing "executive agencies," such as the Education, Audiovisual and Culture Executive Agency (EACEA), the Executive Agency for Competitiveness and Innovation (EACI), and the Executive Agency for the Public Health Programme (PHEA), are primarily entrusted with consulting tasks and providing specific

95. *See* Parliament & Council Regulation 726/2004, pmbl., 2004 O.J. (L 136) 1, 1 (EC) (citing Article 95 of the Treaty establishing the European Community as the authority for the legislation creating the European Medicines Agency).

96. Case C-217/04, U.K. v. Parliament, 2006 E.C.R. I-03771.

97. Parliament & Council Regulation 460/2004, *supra* note 65, pmbl.

98. *See* Case C-217/04, *U.K.*, 2006 E.C.R. I-03771, at ¶ ¶ 14-20.

99. *See id.* ¶ 67. The Court reasoned that Article 95 grants the Community legislature discretion for determining the appropriate methods of harmonizing community laws and regulations. *Id.* ¶ 43. This discretion includes the power to establish an agency. *Id.* ¶ 44. However, such agency's functions must be "closely linked" to the harmonizing legislation. *Id.* ¶ 45.

100. *See Commission Proposal for a Regulation of the European Parliament and of the Council Establishing the European Electronic Communications Market Authority*, at § 3.3, COM (2007) 699 rev. 2 (2007) (establishing Article 95 as the legal basis of the proposed regulation).

101. Council Regulation 58/2003, arts. 1, 2, 7, 2002 (L 11) 1, 2-3 (EC).

services, such as implementing the newly created Community trademark and industrial property regimes.[102] Judged by their auxiliary task and function, the "executive agencies" resemble the first European agencies established in the 1970s.[103]

During the draft process for a European Constitutional Treaty between 2002 and 2004, a frequent topic of discussion was the locus of E.U. agencies in the system of European institutions. While the drafters of the Constitutional Treaty did not grant the E.U. agencies a preferred textual position comparable to the Council, the Commission, and the European Parliament,[104] they nevertheless explicitly included the agencies in the proposed constitutional text, granting judicial review of their actions. For example, Article III-270 of the Draft for the Treaty establishing a Constitution for Europe read:

> (1) The Court of Justice shall review the legality . . . of acts of bodies or agencies of the Union intended to produce legal effects vis-à-vis third parties. . . . (5) Acts setting up bodies and agencies of the Union may lay down specific conditions and arrangements concerning actions brought by natural or legal persons against acts of these bodies or agencies intended to produce legal effects.[105]

The case for institutionalization suffered a serious setback with the defeat of the draft for the E.U. Constitution in the 2005 French and

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102. *See* Europa, Agencies of the EU, Executive Agencies, http://europa.eu/agencies/executive_agencies/index_en.htm (last visited Oct. 12, 2008) (listing current executive agencies); *see also* Paul Craig, *A New Framework for EU Administration: The Financial Regulation 2002*, 68 L. & CONTEMP. PROBS. 107, 116 (2004) (giving examples of tasks that can be assigned to executive agencies).

103. *See supra* Part I.B.1 (discussing functions of the European Centre for the Development of Vocational Training (Cedefop) and the European Foundation for the Improvement of Living and Working Conditions (Eurofound)).

104. *See* Bermann, *supra* note 12, at 446 (commenting on the dearth of references to independent agencies in the Constitutional Treaty); CURTIN, *supra* note 7, at 7 (noting that although the Constitutional Treaty aimed at creating a unified system of administration, it failed to "constitutionalize" such a framework).

105. Draft Treaty Establishing a Constitution for Europe, art. III-270, July 13, 2003, CONV 850/03, *available at* http://european-convention.eu.int/docs/treaty/cv00850.en03.pdf [hereinafter Draft Treaty].

Dutch referenda.[106] Interestingly, one can connect the defeat of the European constitution in France and the Netherlands to broad ignorance of the content of the draft for a Constitutional treaty. A Eurobarometer Poll conducted in 2004 reported that a third of the Europeans polled in the transnational survey had not even heard of the Convention, and that only eleven percent stated that they "broadly [knew] its contents. . . ."[107] This indicates that only a small minority would likely be accurate and characterize the Convention's product as a Constitutional Treaty, as opposed to an international law treaty. It also appears that the voters largely based their decisions on distrust of the E.U., possibly associating the European Union with lacking transparency and participation, ineffective bureaucracy, and unjustified transfers of sovereignty.[108]

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106. *See, e.g.*, *Dutch Say 'No' to EU Constitution*, BBC NEWS, June 2, 2005, http://news.bbc.co.uk/2/hi/europe/4601439.stm (reporting that voters' concerns revolved around too much centralized power at the expense of national sovereignty).

107. *See* EUROPEAN COMMISSION, SPECIAL EUROBAROMETER 214: THE FUTURE CONSTITUTIONAL TREATY 3-4 (Mar. 2005), *available at* http://ec.europa.eu/public_opinion/archives/ebs/ebs_214_en.pdf [hereinafter SPECIAL EUROBAROMETER 214]; *see also* Achim Hurrelmann, *European Democracy, the 'Permissive Consensus' and the Collapse of the EU Constitution*, 13 EUR. L.J. 343, 353 (2007) (providing further empirical studies and polls illustrating an EU-wide dichotomy between trust in national institutions and E.U. institutions); Neil Walker, *After the Constitutional Moment*, 16 (The Federation Trust Constitutional Online Paper Series No. 32/03 2003), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=516783 (suggesting that, whatever the causes of the voters' ignorance of the treaty's contents, it is indicative of the voters' "skepticism about the viability of European political community").

108. *See* SPECIAL EUROBAROMETER 214, *supra* note 107, at 27 (reporting 37% Europeans who voted "no" in the referenda on the Constitutional Treaty were fearful of the "loss of national sovereignty); *see also* Mark Bovens, *New Forms of Accountability and EU-Governance*, 5 COMP. EUR. POL. 104, 104 (2007) (attributing the low level of legitimacy of the E.U., in part, to past "accountability deficits" and the current debate over transparency and accountability in EU governance); Gilles Ivaldi, *Beyond France's 2005 Referendum on the European Constitutional Treaty: Second-Order Model, Anti-Establishment Attitudes and the End of the Alternative European Utopia*, 29 W. EUR. POL. 47, 49 (2006) (connecting the failure of the referendum in France to an anti-Establishment attitude and a backlash against the process of European integration).

C. DECENTRALIZATION AND DECONCENTRATION

The broad establishment of E.U. agencies affected the organizational dimension of European administrative law in various ways. Presumably the two most important consequences are the deconcentration and decentralization of European administration. First considering the deconcentrating effects, European administration is no longer processed only by the Commission and institutions such as the European Central Bank, but now also by European Union agencies. The agencies are not regularly managed by officials of the Commission, but rather by independent executive directors and management boards that are nominated in a specific procedure, involving various actors such as the Member States and the European parliament.[109] The notion that most of the tasks of newly established E.U. agencies were not formerly administered by the European Commission, but instead by the E.U. Member States, does not mitigate the deconcentration-thesis, because this claim draws primarily on the crucial organizational innovation of independent administrative entities beside the Commission, rather than on the federal division of powers between the European level and Member States.

Second, the new agency structure decentralizes European administration. The new agencies were not set up in Brussels, but were instead established in cities all over Europe, including Thessaloniki in Greece (European Reconstruction Agency, 2000), Valenciennes and Lille in France (European Railway Agency, 2004), Vigo in Spain (Community Fisheries Control Agency, 2005), and Stockholm in Sweden (European Centre for Disease Prevention and Control, 2005).[110] Through the decentralized agencies, the Member States are able to participate directly in the day-to-day practice of

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109. *See* CRAIG, *supra* note 3, at 172-73 (describing the nomination and appointment process for agency leadership, and the degree to which the Commission's power to control appointments to agency leadership positions has declined in response to demands for increased independence and expertise in the agency's area of authority).

110. *See* EUROPEAN COMMISSION, EU AGENCIES: WHATEVER YOU DO, WE WORK FOR YOU 3-27 (2007), http://bookshop.europa.eu/eGetRecords?Template=en_publication_details&UID=533745 [hereinafter EU AGENCIES] (providing contact details and work descriptions for the various EU agencies).

European administration, rather than merely through their delegates to Brussels-based authorities.[111] The European Commission finds particular value in the notion that "the spread of agencies beyond Brussels and Luxembourg adds to the visibility of the Union."[112] Even though the new agencies were not excessively large bureaucracies—oftentimes they count between 300 and 500 employees—there were undeniably positive socio-economic effects accompanying each new agency, in terms of construction work on new buildings, new jobs in sciences and services, visitors to the agency, and media publicity for the hosting city. As a consequence, the Member States apparently strive to host as many agencies as possible. A notable story in this vein happened in 2002, when the European Commission intended to set up the new European Food Safety Agency (EFSA) in Finland. This plan was strongly opposed by Italian Prime Minister Silvio Berlusconi, who finally succeeded in his colorful campaign in favor of the city of Parma.[113] In exchange, the European Chemicals Agency was ultimately established in Helsinki.[114]

D. THE LOCUS OF AGENCIES IN EUROPE'S INTEGRATED ADMINISTRATION

The institutional changes that occurred over time formed a specific supranational profile of administration. Neither the Comitology committees nor the E.U. agencies took the shape of autonomous

111. *See* Hofmann & Türk, *supra* note 23, at 87 (characterizing decentralized European agencies as forums for facilitating co-operation between national and supranational authorities to improve integration and competence in various regulatory fields of operation).

112. *The Way Forward*, *supra* note 4, at 2.

113. Laurie Buonanno, *The Creation of the European Food Safety Authority, in* WHAT'S THE BEEF: THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY 259 (Christopher Ansell & David Vogel eds., 2006) (recounting briefly the opposition to establishing the EFSA in Finland, and Finland's argument that member states lacking an E.U. agency were entitled to preference in site selection for newly authorized agencies under the Edinburgh Council decision of 1992, an argument that was ultimately overcome by President Berlusconi's efforts on behalf of Parma).

114. *See* EU Business, European Chemicals Agency ECHA - Guide, http://www.eubusiness.com/Chemicals/echa-guide.01/ (last visited Oct. 12, 2008) (reporting that Finland was lobbying to have either the Chemicals Agency or the Food Safety Authority located in Helsinki).

federal entities. Instead, both appear as nodal points within an interacting system of a European "network administration," encompassing supranational and national regulatory authorities.[115] Broadly speaking, this picture of executive powers exercised by the Council of ministers forming "the government," the formal bureaucracy, and a "plethora of other agencies and firms to which power has been transferred," mirrors the nature of the E.U., which has always been characterized by an interinstitutional balance of power rather than the separation of powers.[116] Recently Sabino Cassese identified the agencies as the second of three forms of cooperation between the European level and individual national administrations. Cassese's account distinguishes between:

> [1] [J]oint administration . . . characterized by . . . a hybrid—part supranational, part national—administrative apparatus[117]. . . . [2] [D]ecentralized administration . . . characterized by parallel, non-exclusive legal powers vested in both the Community and the Member States, together with a single administrative apparatus [that is] a European agency[118] . . . . [And] [3] [T]he regulatory concert [in which] national and supranational authorities make up a common organization.[119]

An additional pattern of administrative cooperation is made up of transgovernmental networks comprised of national regulatory

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115. *See* Hofmann & Türk, *supra* note 23, at 88 (characterizing European agencies as unlike the independent, autonomous model employed by U.S. regulatory agencies in that they each typically engage in a wide range of diverse activities that frequently intersect and overlap with other agencies' interests to form a diffuse network of administration).

116. *See* Paul Craig, *European Governance: Executive and Administrative Powers Under the New Constitutional Settlement*, 3 INT'L J. CONST. L. 407, 434-35 (2005) (presenting arguments for and against shared/divided executive power in the EU).

117. *See* Cassese, *supra* note 10, at 22 (citing "the administration of structural funds as an example of this form of cooperation").

118. *See id.* (declaring European efforts to combat illegal drugs to be an example of this form of decentralized administration).

119. *See id.* (providing as an example of the regulatory concert the telecommunication sector and the functioning of the heads of Member State authorities as members of a "European Regulatory Group" in Brussels).

authorities, oftentimes formally embedded in the supranational policymaking process.[120]

II. ACCOUNTABILITY FEATURES

The rise of the agency system did not remain unchallenged. Accountability concerns were especially linked to judicial review, and to the delegation limits of the *Meroni* doctrine.[121] Yet a closer inquiry into the profiles of specific E.U. agencies reveals quite a remarkable and diverse system of accountability features. The European Commission undertook several attempts to overcome the diversification of accountability regimes, which remained largely unsuccessful.[122] Despite the ongoing diversity, the accountability regimes significantly strengthened in the latest generation of E.U. agencies during the 2000s. This increase corresponds with the overall evolution of E.U. agency powers from the 1970s over the 1990s and beyond.

A. UNITY AND DIVERSITY OF ACCOUNTABILITY REGIMES: TWO CASE STUDIES

The presentations of the following case studies are to illustrate the convergences and divergences in the institutional design of European agencies in detail, focusing particularly on the accountability

120. *See* Burkard Eberlein & Abraham Newman, *Escaping the International Governance Dilemma? Incorporated Transgovernmental Networks in the European Union*, 21 GOVERNANCE 25, 26 (2008) (arguing for a superior approach to analyzing issues of international coordination, especially in the EU context, where national governments have not entirely transferred regulatory power to the supranational institutions).

121. *See* CURTIN, *supra* note 7, at 9; HARLOW, *supra* note 79, at 75 (arguing that because most agencies' powers were limited to information-gathering functions, they presented "little threat to either transparency or accountability"); *The Way Forward*, *supra* note 4, at 5 (reiterating the *Meroni* limitations on agencies' powers and stressing the continuing "need for clear lines of accountability to govern agencies' actions").

122. *See Commission White Paper on European Governance*, *supra* note 81, at 3, 6 (proposing a plan to foster consistency in E.U. policy); *Communication from the Commission, The Operating Framework for the European Regulatory Agencies*, *supra* note 82, at 2 (calling for European institutions to be refocused in terms of responsibilities and current practices); *Draft Interinstitutional Agreement*, *supra* note 89, at 2 (seeking to strengthen E.U. agencies by establishing "common core of principles and rules" and creating a "clear system of controls").

regimes[123] of the European Medicines Agency (EMEA) in London, and the European Aviation Safety Agency (EASA) in Cologne, as two significant examples of E.U. agencies. The institutional design of the EMEA and the EASA are representative for the development of competences and control mechanisms over time. The EMEA stems from the wave of agency founding in the early 1990s, and is an agency with limited formal powers, but great de facto powers.[124] To the contrary, the EASA was founded in 2002 and is currently the most powerful European agency, particularly because it is the first authority beyond the Commission with formal licensing powers.[125] Functionally, both agencies deal with the licensing of products—the former with pharmaceuticals and the latter with airplanes. But as will become clear, they do it in very different ways. Both agencies are entrusted with tasks that were formerly exercised on the national level,[126] and both operate on a fee-based mechanism, whereby the fees that they charge cover most of the costs.[127]

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123. *See* Jerry L. Mashaw, *Accountability and Institutional Design: Some Thoughts on the Grammar of Governance*, *in* PUBLIC ACCOUNTABILITY: DESIGNS, DILEMMAS AND EXPERIENCES 115, 118-20 (Michael W. Dowdle ed., 2006) (defining accountability regimes as legal and social constraints applied across various contexts).

124. *See* EU AGENCIES, *supra* note 110, at 22 (describing European Medicines Agency's role as a facilitator in licensing pharmaceutical products while the Commission retains licensing power).

125. *See id.* at 8 (describing the broad and growing responsibilities of the EASA).

126. JOHN ABRAHAM & GRAHAM LEWIS, REGULATING MEDICINES IN EUROPE: COMPETITION, EXPERTISE AND PUBLIC HEALTH 43, 80 (2000); DANIEL RIEDEL, DIE GEMEINSCHAFTSZULASSUNG FÜR LUFTFAHRTGERÄT *passim* (2006).

127. *See Statement of Revenue and Expenditure of the European Medicines Agency for the Financial Year 2005,* 2005 O.J. (L 096) 366 [hereinafter *Statement of Revenue*] (detailing EMEA revenues for financial year 2004 and showing about sixty-seven percent of revenues in fees); European Aviation Safety Agency, *Annual Accounts for the Year 2006*, at 5, http://www.easa.eu.int/ws_prod/g/doc/Finance/Annual%20accounts%202006_MB0907.pdf (reporting EASA's income from fees in 2006 at about fifty percent of total operating revenue); *see also* Vos, *Agencies and the European Union*, *supra* note 55, at 121-22 (noting that although EMEA revenues from fees have grown over the years, the agency strives to stay independent from the pharmaceutical industry by relying at least in part on E.U. funding); *Statement of Revenue*, *supra*, at 5 (reporting EASA's income from fees in 2006 at about fifty percent of total operating revenue).

1. European Medicines Agency (EMEA)

The E.U. primarily entrusted the European Medicines Agency and its approximately 440 staff members[128] with providing opinions in the field of pharmaceutical licensing.[129] The "Centralized European Procedure" provides the applicant (usually a pharmaceutical company such as Novartis, Pfizer or BASF) with a license that is valid in all E.U. Member States, and is mandatory for an increasing range of pharmaceuticals explicitly mentioned in the basic regulation.[130] For all other pharmaceuticals the "Centralized European Procedure" is voluntary. The national pharmaceutical authorities remain in existence, and remain indispensable in terms of law enforcement, even if the significance with regard to licensing is decreasing.[131] Having a European license makes perfect sense in most cases. According to the association of researching pharmaceutical companies in Germany, the invention and development of every new pharmaceutical takes an estimated ten to twelve years, and costs 800 million Euros.[132] Since no domestic European market is big enough for refinancing these expenses, the economic success of every single pharmaceutical depends on its distribution in other European countries and beyond.[133] The European license is formally issued by the European Commission—

128. EU AGENCIES, *supra* note 110.

129. *See id.*; Parliament & Council Regulation 726/2004, *supra* note 95, art. 57 (charging EMEA with giving scientific advice to Member States and E.U. institutions).

130. *See* Parliament & Council Regulation 726/2004, *supra* note 95, art. 6, Annex (extending the centralized Procedure to new pharmaceuticals including diabetes, aids, cancer and neurodegenerative disorders).

131. *See* European Commission, *Enterprise and Industry, Enterprise Europe No 19, Single Market, Health in Safety* (2005), http://ec.europa.eu/enterprise/library/enterprise-europe/issue19/articles/en/topic10_en.htm (estimating EMEA's current share of scientific assessments of medicines in E.U. at about sixty percent and predicting its share to increase to over ninety percent in the future).

132. Verband Forschender Arzneimittelhersteller E.V., Die Revision der EG-Arzneimittelgesetzgebung – Herausforderungen und Chancen für Patienten, Zulassungsbehörden und die pharmazeutische Industrie, http://www.vfa.de/de/politik/artikelpo/revision2005.html (last visited Oct. 12, 2008).

133. *See* ABRAHAM & LEWIS, *supra* note 126, at 31-33, 81-82 (explaining the pharmaceutical industry's lobbying efforts for centralized transnational regulation as resulting from political pressure to reduce cost of medicines).

which relies heavily on the agency.[134] The vote of the agency and its sub-committees cannot be ignored.[135] In the words of a leading expert on European regulatory regimes: "the Commission systematically rubber-stamps EMEA recommendations—apparently without even discussing them . . . ."[136]

The agency hosts several expert committees comprised of representatives—usually members of the national medicines authorities—from the Member States.[137] Practical examples include the Committee for Medicinal Products for Human Use (CHMP), and additional specific Committees for Pharmaceuticals for Veterinary Use and Herbal Pharmaceuticals.[138] Within the licensing process the Committees play a pivotal role, since within the agency they are often entrusted with developing and giving the substantive opinion for a certain pharmaceutical.[139] The opinion of the Committee includes a recommendation to the European Commission to either grant or refuse the permission for the new pharmaceutical, and is published on the EMEA's website ("recommendation for EU-approval").[140] Regularly the next and final step is granting the market

134. *See* Parliament & Council Regulation 726/2004, *supra* note 95, art. 10 (authorizing the European Commission to approve medicinal products for human use based on the guidance of the EMEA).

135. *See* Vos, *Agencies and the European Union*, *supra* note 55, at 121 (stating that while the EMEA's powers are advisory, its scientific expertise bears heavily in Commission decision making).

136. Dehousse, *supra* note 2, at 223.

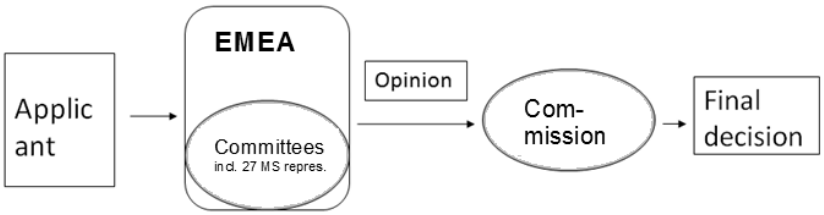
137. Parliament & Council Regulation 726/2004, *supra* note 95, art. 87.

138. *See* European Medicines Agency, About EMEA – Structure, *supra* note 63 (listing five committees).

139. *See* JÜRGEN FEICK, REGULATORY RATIONALISATION AND LEGITIMATION IN THE FACE OF INTERESTS, INFLUENCE AND INSTITUTIONAL DE-POLITICISATION – MARKET ENTRY REGULATION FOR PHARMACEUTICALS IN THE EU 6-8 (2004), http://www.mpifg.de/people/jf/downloads/Conference%20Paper%20Januar%202003.pdf (noting that "the Centralized Procedure is reserved for especially innovative medicinal products").

140. *See* European Medicines Agency, Human Medicines – CHMP Summaries of Opinion, http://www.emea.europa.eu/htms/human/opinion/opinion.htm (last visited Oct. 12, 2008) (listing positive and negative opinions of the committee). *See also* Sebastian Krapohl, *Credible Commitment in Non-Independent Regulatory Agencies: A Comparative Analysis of the European Agencies for Pharmaceuticals and Foodstuffs*, 10 EUR. L.J. 518, 531-33 (2004) (detailing the path pharmaceutical licensing applications take for an ultimate decision in favor or against).

FIGURE 1: CENTRALIZED EUROPEAN PROCEDURE FOR PHARMACEUTICAL LICENSING (SIMPLIFIED)



authorization in the form of a Commission Decision issued by the European Commission.[141]

Against the backdrop of the small administrative body of the European Medicines Agency, the Committee-procedure is a remarkable mechanism of incorporating Member State expertise into the agency. Making use of knowledge and experience gathered in the E.U. Member States appears to efficiently deal with the scarcity of the agency's own human resources.[142] The very same mechanism of integrating national officials into the agency's licensing procedure also enables the Member State to exercise informal controls into the day-to-day-practice on the European level.[143]

One very controversial aspect is whether judicial review is available against a negative agency-opinion on a specific pharmaceutical. So far the European Courts only grant standing for suits contesting EMEA *decisions*. For example in the 2006 *Albert Albrecht* case the European Court of First Instance granted standing

141. *See* Antoine Cuvillier, *The Role of the European Medicines Evaluation Agency in the Harmonisation of Pharmaceutical Regulation*, *in* PHARMACEUTICAL MEDICINE, BIOTECHNOLOGY AND EUROPEAN LAW 137, 143 (Richard Goldberg & Julian Lonbay eds., 2000) (explaining the centralized procedure for authorizations under the EMEA, beginning with application directly to the EMEA and culminating in the final decision by the European Commission).

142. *See* Mario P. Chiti, *Forms of European Administrative Action*, 68 L. & CONTEMP. PROBS. 37, 45 (2004) (observing that the cooperation between national and European agencies "obviates the need to expand the core civil service at the European level").

143. *See* CRAIG, *supra* note 3, at 178 (discussing the roles of players at the national, Community, and international level and how their interactions can affect policymaking and implementation).

to a joint venture of pharmaceutical companies against an EMEA decision requiring a company to provide certain information and to pay fees.[144] To the contrary, the European Courts have constantly refused standing against EMEA opinions, and always referred to the formally decisive act of the European Commission.[145] Some lawyers have challenged this jurisprudence, claiming that opinions issued by the EMEA could be challenged under Article 230, Section 1 of the TEC.[146] Since the text of Article 230 does not include actions of agencies, extensive interpretation of this provision would be required. Indeed, several ECJ cases provide for an extended interpretation of Article 230. In *Les Verts*, the ECJ ruled in 1986 that an act of the European Parliament could be subject to judicial review despite the lack of a specific provision in the TEC.[147] As an argument, the ECJ referred to the community's commitment to the rule of law.[148] In addition, the European Court of First Instance recently stated, in *Sogelma*, that this ruling is not limited to the institutions in Article 7 TEC.[149] Yet the Court of First Instance rejected the idea of an extended Article 230 TEC interpretation in 2003 in the *Olivieri* case.[150] In that case Ms. Olivieri, a physician

144. *See* Case T-19/02, Albert Albrecht GmbH & Co. KG v. Comm'n, 2006 E.C.R. 0, ¶¶ 31, 41 (observing that the questions of law raised in this action, including the EMEA's capacity to be sued, "have not yet been definitively decided").

145. *See*, *e.g.*, Case T-133/03, Scherig-Plough Ltd. v. Comm'n, 2008 O.J. (C 37) 32, ¶¶ 1, 2 (dismissing an action for the annulment of an EMEA measure refusing a type variation of a pharmaceutical).

146. Consolidated Version of the Treaty Establishing the European Community, art. 230, 2002 O.J. (C 325) 33 [hereinafter Consolidated Treaty] (declaring that "[t]he Court of Justice shall review the legality of acts adopted jointly by the European Parliament and the Council, of acts of the Council, of the Commission and of the ECB, other than recommendations and opinions, and of acts of the European Parliament intended to produce legal effects vis-à-vis third parties").

147. *See* Case 294/83, *Patri Ecologiste 'Les Verts'*, 1986 E.C.R. 1339, ¶¶ 21, 23-25 (holding that neither Member States nor E.U. institutions can avoid judicial review of measures adopted by them) .

148. *Id.*

149. Case T-411/06, Sogelma v. European Agency for Reconstruction, 2008 E.C.R. 0, ¶ 37 (extending ECJ's holding in *Les Verts* to any E.U. institution as long as they are "endowed with the power to take measures intended to produce legal effects vis-à-vis third parties").

150. *See* Case T-326/99, Nancy Fern Olivieri, v. Comm'n, 2004 O.J. (C 71) 39 (dismissing the plaintiff's application as inadmissible); *see also* Case T-326/99, Nancy Fern Olivieri v. Comm'n, 2000 E.C.R. II-1985 (including a larger

and distributor of pharmaceuticals, challenged the negative opinion that the EMEA and its Committee for Proprietary Medicinal Products (CPMP) issued on the pharmaceutical she had applied for.[151] In order to meet the admissibility standards, Ms. Olivieri relied in particular on the ECJ's ruling in *Les Verts*, and argued that the EMEA was an "auxiliary body vested with specific powers of an administrative nature" (in the sense of earlier rulings of the ECJ), subject to judicial review according to Article 230.[152] However, the crucial point for an applicant like Ms. Olivieri is the legally binding effect of the EMEA opinion at stake, which here she was unable to prove.[153]

Because of the constant rejection of motions directly against negative EMEA opinions, applicants filed a large majority of motions challenging dismissals of pharmaceutical applications directly against the succeeding Commission Decision. The central case in that area is the 2002 *Artegodan* decision,[154] where the Court of First Instance not only agreed to hear a claim against a negative decision of the Commission on a pharmaceutical application, but also held that effective review requires exploration beyond the Commission's formal decision into the findings of the agency and its

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consideration of the standing issue heard during the interim hearing).

151. Case T-326/99, *Olivieri*, 2000 E.C.R. II-1985, ¶¶ 14-24.

152. Case T-326/00, Nancy Fern Olivieri v. Comm'n, 2003 E.C.R. II-6053, ¶ 49.

153. *See id.* ¶¶ 53-54 (finding that because EMEA's opinion in that case was not a final but an intermediate measure, it could not be challenged under *Le Verts*). *See also* Case T-264/07, CSL Behring v. Comm'n, 2007 O.J. (C 235) 22 (challenging a letter sent by the EMEA to the plaintiff, who regarded it as the agency's legally binding refusal to continue the procedure for designating the applicant's medicinal product as an orphan medicinal product). This is another interesting recent action brought up by a German pharmaceutical company directly against the EMEA which hasn't been decided yet and approaches the problem on the basis of slightly different facts. *Id.*

154. *See* Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00, & T-141/00, Artegodan GmbH v. Comm'n, 2003 O.J. (C 19) 53 (seeking annulment of a Commission decision to withdraw marketing authorizations for certain products); *see also* Case T-237/03, Merck Sharp & Dohme v. Comm'n, 2006 O.J. (C 86) 48; Case T-179/00, A. Menarini – Industrie Farmaceutice Riunite Srl v. Comm'n, 2002 O.J. (C 202) 30 (annulling a Commission Decision to disallow the plaintiff's request to display its logo on the packaging for a pharmaceutical product).

committee, here the EMEA and the CPMP.[155] With that, the court acknowledged the tremendous factual importance of the agency's opinion, and stated that the Commission would necessarily have to follow the agency—unless it could come up with elaborate reasoning pointing to the contrary.[156]

The *Artegodan* case also shows another feature of legal accountability, which is the margin of deference that the European Courts grant toward the agency's action.[157] The higher the margin of deference, the less legally accountable the agency is.[158] In the context of technology and risk regulation there regularly are strong forces pushing for judicial deference, in order to enhance the agency's flexibility and strengthen the scientific expertise. The groundbreaking judgment in the American context is *Chevron*, where the U.S. Supreme Court justified deference to the statutory interpretation of an agency on the grounds of agency expertise and democratic accountability.[159] Yet the *Artegodan* case indicates that the Court of First Instance can grant deference to the scientific judgment of the EMEA only to a limited extent. Whereas the ECJ generally acknowledges the necessities implied in the EU's commitment to the precautionary principle, it does point to the limits of deference as well, and states: "[t]hat choice must, however comply

155. Case T-74/00, Artegodan GmbH v. Comm'n, 2002 E.C.R. II-494, ¶¶ 197-200 (declaring that any illegality in the CPMP's opinion will render the Commission's decision based on it unlawful).

156. *Id.* ¶¶ 199, 201, 211, 220 (elaborating that in addition to evaluating the CPMP's opinion, the court must review whether the Commission has, in turn, exercised its discretion).

157. Case C-39/03 P, Comm'n v Artegodan GmbH, 2003 O.J. (C 202) 2 (dismissing the appeal of the European Commission against the judgment of the Court of First Instance).

158. *See* Peter L. Lindseth, *Democratic Legitimacy and the Administrative Character of Supranationalism: The Example of the European Community*, 99 COLUM. L. REV. 628, 692-96 (1999) (reciting an ECJ decision that prohibited the Commission from issuing decisions on scientific matters without consulting relevant scientific committees and arguing that such decisions grant too much power to politically unaccountable bodies).

159. *See* Chevron v. National Resources Defense Council, 467 U.S. 837, 843 (1984) (holding that deference should be given to agency decisions in instances where a statute is silent or ambiguous on a particular issue, and the agency's interpretation is reasonable). *See generally* Eric Biber, *The Importance of Resource Allocation in Administrative Law*, 60 ADMIN. L. REV. 1 (2008) (exploring the implications of *Chevron* deference for an agency's accountability).

with the principle that the protection of public health, safety and the environment is to take precedence over economic interests . . . ."[160] Thus the ECJ examines the scientific findings of the EMEA and its Committee on which the Commission's decision was based, and explores whether the scientific findings were sufficiently conclusive.[161] On the national level, judicial review is available against decisions of national authorities that are implementing or enforcing the European standards. However, in the day-to-day practice of the national courts, most of the cases in which individuals or organizations are challenging the national authorities with regard to the enforcement of European pharmaceutical law are different.[162] It is rather that the non-enforcement of European law is claimed. This happens typically when the national authorities are prohibiting the purchase or use of a pharmaceutical which has been licensed by the European Commission (on basis of an EMEA recommendation). In response, the national pharmaceutical authority will argue that it is making use of an exceptional entitlement provided directly in the European regulation or directive, such as on the grounds of public health and safety.[163]

2. European Aviation Safety Agency (EASA)

Like the EMEA, the EASA is entitled to issue the certificates for the licensed products under its own name and authority. The E.U. established the EASA in the early 2000s under the political rationale

160. Case T-74/00, *Artegodan GmbH*, 2002 E.C.R. II-494, ¶ 186.

161. *See id.* ¶ 200 (recognizing that while it cannot "substitute its own assessment for that of the CPMP," the court can determine whether the agency's opinion was based on sufficient reasons and whether there was a causal link between those reasons and the agency's ultimate conclusions). *See also* MARIA LEE, EU ENVIRONMENTAL LAW: CHALLENGES, CHANGE AND DECISION-MAKING 104-05 (2005) (finding courts use the precautionary principle to conduct detailed reviews of the evidence and facts an agency used to reach a decision); CRAIG, *supra* note 3, at 429-32 (analyzing judicial review in matters of law, fact, and discretion under EU law, and the close degree of scrutiny required of factual findings).

162. *See, e.g.*, XYZ v. Schering Health Care Ltd., (2002) EWHC 1420 (QB), 2002 WL 1446183, ¶¶ 2, 15-16 (claiming certain representations of pharmaceutical companies in the U.K. diverged from an opinion of the CPMP).

163. *See*, *e.g.*, Council Directive 1993/42, Art. 8 Sec. 1 (allowing for appropriate interim measures to withdraw medical devices from the market, if these devices may compromise the health and/or safety of patients or users).

that a genuine European single market in air transport services demands common safety rules and harmonized standards of implementation.[164] The agency is located in Cologne, and has about 400 staff.[165] The national aviation authorities are embedded in an emerging administrative network built up by EASA and the relevant Member State agencies, which maintain a set of competences. From a functional point of view, EASA is both a decision-making and a quasi-rulemaking agency. In its decision-making function, the agency issues type-certificates with regard to the airworthiness of specific airplanes, and issues environmental certificates for aircraft products.[166] In 2008, the licensing powers of the EASA were further extended to include the licensing of pilots on the basis of their compliance with essential requirements on theoretical knowledge, practical skill, language proficiency and experience,[167] and the regulation of the operation of aircraft.[168]

The EASA airworthiness license is a model license for the airplane type in general, which EASA crafts according to the model license is issued by the Member States. Like the EMEA, the EASA is supported by two consultative bodies. First there is the Advisory Group of National Aviation Authorities (AGNA), second there is the Safety Standards Consultative Committee (SSCC), which is mostly comprised of private experts coming from the airplane industry.[169]

In the rulemaking area, there are patterns similar to the context of the EMEA. There is also an ongoing tension between limited formal competences and tremendous de facto powers. The EASA has several tasks at different legal levels. First, the agency makes

164. *See* Parliament & Council Regulation 216/2008, *supra* note 66, pmbl, ¶ 1 (stating that common aviation regulations will promote "free movement of goods, persons and organisations in the internal market").

165. *See* EUROPEAN AVIATION SAFETY AGENCY, MULTI-ANNUAL STAFF POLICY PLAN 2008–2010 4, 9 (2007), *available at* http://www.europarl.europa.eu/meetdocs/2004_2009/documents/dv/tran20070410_easa_staff_en/tran20070410_easa_staff_en.pdf (reporting total staff of 467 in 2007).

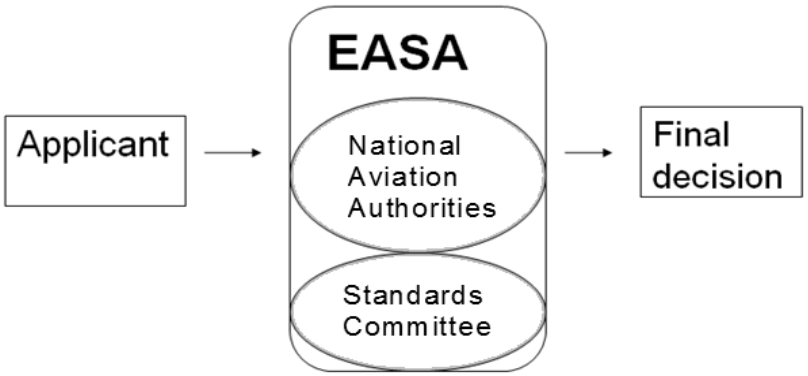
166. *See* Parliament & Council Regulation 216/2008, *supra* note 67, arts. 18, 20 (requiring the EASA to issue airworthiness and environmental certification specifications according to guidelines established in the regulation).

167. *See id.* art. 7, Annex III (establishing certification guidelines for pilots).

168. *See id.* art. 8, Annex IV (setting standards for aircraft operation).

169. *See id.* art. 65 (authorizing a committee empowered to assist the Commission in the decision-making process).

FIGURE 2: EUROPEAN PROCEDURE FOR AIRWORTHINESS LICENSES (SIMPLIFIED)



proposals for changes of the Agencies Basic Regulation, which also include the basic requirements for the security of airplanes.[170] Second, the agency proposes rules that are formally issued by the Commission.[171] Third, the agency issues under its own name "certification specifications, including airworthiness codes and means of compliance . . . to be used in the certification process."[172] The EASA proposals are not considered binding on all three levels;[173] however, it seems fair to classify the EASA as a quasi-rulemaking agency.[174] In spite of the formal classification, the factual

170. *See id.* art. 18, ¶ 2 (requiring the Agency to prepare recommendations for amending the Regulation 216/2008 for the Commission).

171. *See id.* art. 19, ¶ 1 (authorizing the Agency to develop certification specifications and guidance material to be used in the certification process); Commission Regulation 1702/2003, pmbl., ¶ 8, 2003 O.J. (L 243) 6 (EC) (laying down implementing rules for the airworthiness and environmental certification of aircraft in accordance with EASA's opinion); Commission Regulation 335/2007, pmbl., ¶ 8, 2007 O.J. (L 88) 40 (EC) (amending Regulation (EC) No 1702/2003 and acknowledging that it is doing so based on EASA's opinion).

172. *See* Parliament & Council Regulation 216/2008, *supra* note 66, art. 19, ¶ 2 (providing that Agency proposals must reflect the state of the art and best industry practices, as well as be updated in accordance with worldwide aircraft experience).

173. *See id.* pmbl., ¶ 22 (stating that the EASA should "assist" the Commission in the preparation of the necessary legislation).

174. *See* Deirdre Curtin, *Delegation to EU Non-Majoritarian Agencies and Emerging Practices of Public Accountability*, *in* REGULATION THROUGH AGENCIES IN THE EU, *supra* note 64, at 88, 95 (commenting on the degree of independence of the new regulatory agencies that are allowed to promulgate rules that are binding

significance of the EASA-proposals is tremendous, because the airplane industry is complying with the agency's specifications—whether they are declared to be formally binding or not.[175] Another point that shows the de facto character of a real rule-making agency is that the EASA is the first agency with an explicit "rule-making department" that is headed by a "rule-making director."[176] Moreover, the EASA is the first entity in the history of E.U. agencies that has powers to conduct "standardisation inspections of Member States competent authorities."[177] The EASA is also empowered to charge fees for its work.[178]

Interestingly, the expansion of tasks and competences in the institutional design of the EASA, as compared to the 1990s agencies, is accompanied by a simultaneous increase of formalization and juridification. For example, the rule-making process is subject to a quite remarkable notice and comment system that is provided through the EASA website.[179] The judicial review is also tremendously enhanced into a two-step-system. An internal Board of Appeals within the agency will grant access to rejected applicants for airworthiness certificates.[180] The Board of Appeals is ready to hear appeals against agency decisions pursuant to Articles 15

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on third parties); *see also* Larouche, *supra* note 64, at 95 (contending that European Regulatory Agencies were to be regarded as autonomous from the Commission but performing part of the Commission's own executive duties).

175. *See* Parliament & Council Regulation 216/2008, *supra* note 66, art. 4 (requiring industry compliance with the Basic Regulation and, therefore, with EASA's specifications issued in accordance with the Regulation).

176. EASA, Rulemaking Directorate, http://www.easa.eu.int/ws_prod/r/r_main.php (last visited Oct. 12, 2008) (listing the department's structure and competencies).

177. *See* Parliament & Council Regulation 216/2008, *supra* note 67, art. 54 (requiring Member States to "submit to the inspections and . . . ensure that bodies or persons concerned also submit to them"); Vos, *supra* note 55, at 121 (noting EASA was the first EU agency that was empowered to conduct inspections of Member States).

178. *See generally* Commission Regulation 593/2007, 2007 O.J. (L 140) 3 (EC) (providing that fees and charges may be levied by the Agency only and that Agency revenues and expenditures should be in balance).

179. *See* Parliament & Council Regulation 216/2008, *supra* note 67, art. 52 (requiring EASA to consult with interested parties and Member States when issuing its opinions, specifications, and guidelines).

180. *See id.* arts. 40, 44 (establishing the Board of Appeals and allowing the agency to suspend the application of a challenged decision).

(Airworthiness and Environmental Certification), 46 (Investigations or Undertakings for application of Article 15) or 53 (Fees or charges regulation). A negative decision of the Board of Appeals is appealable to the Court of First Instance.[181] By and large the affected European industries thoroughly evaluated the system of judicial review established in the EASA Basic Regulation. Several times the EASA system was recommended as a role model for the future design of succeeding agency foundations, such as in the case of the European Chemicals Agency.[182] The number of ECJ and CFI cases involving the EASA has remained relatively small thus far, partly because the agency was only recently established and partly because the manufacturers involved are trying to solve potential conflicts long before even thinking of a lawsuit. One of the first cases involving the EASA as a party was the *Andrade Sena* case, which dealt not with the licensing process, but with the internal organization of the agency.[183]

A recent ECJ case which exemplifies the practical importance and application of the rulemaking activities of the EASA is in the Danish case *Kramme v. SAS Scandinavian Airlines Denmark A/S*.[184] In this case a passenger sued the airline for compensation for a canceled flight,[185] thereby demanding remedies granted in a European regulation.[186] The norms governing the case included an implementing Commission regulation that incorporated standards

181. *See id.* art. 50 (allowing actions for the annulment of EASA's decisions to be brought before the Court of Justice, but only after all appeals within the Agency have been exhausted); *see also id.* art. 51 (opening up the way to the Court of Justice in case the EASA fails to take a decision).

182. *See* Cefic: European Chemical Industry Council, A Strengthened Role for the European Chemicals Agency (Sept. 15, 2005), http://www.cefic.be/files/publications/11.doc (arguing that the European Chemicals Agency, just like EASA, needs the power to issue legally binding decisions).

183. *See* Case T-30/04, João Andrade Sena v. European Aviation Safety Agency, 2005 O.J. (C 171) 35 (dismissing the challenge to EASA's rejection of plaintiff's candidacy for the post of Executive Director).

184. *See* Case C-396/06, Eivind F. Kramme v. SAS Scandinavian Airlines Danmark A/S, 2006 O.J. (C 294) 52.

185. *Id.* ¶¶ 17-18.

186. *See* Parliament & Council Regulation 261/2004, art. 5, 2004 O.J. (L 46) 1 (establishing common rules on compensation and assistance to passengers in the event of denied boarding). The Regulation also limited compensation if the cancellation was "caused by extraordinary circumstances which could not have been avoided even if all reasonable measures have been taken." *Id.* art. 5(3).

developed by the EASA on continuing airworthiness and maintenance organization approvals.[187] For actors other than the company applying for the airworthiness certificate, the European Court of Justice is much harder to access. This is especially true with regard to the consumers who are affected by EASA decisions every time they take a plane. In such a case the before-mentioned rules of the EASA Basic Regulation do not provide access to the board of appeals, and the subsequent link to the European Court of Justice does not work either. Similarly there are no provisions for other than the applying aircraft company to challenge the legality of an environmental certificate. Further, the European Treaties do not provide for judicial review either because Art. 230 Section (4) TEC[188] as interpreted by the ECJ does not apply.[189]

B. MULTIPLE-PRINCIPAL-SYSTEM

Beyond the judicial controls there is a broad set of political and financial accountability mechanisms. One of the most notable features is the structural relationship between agents and principals. Whereas in the United States administrative agencies on the federal level are accountable to President and Congress as their two major principals, in Europe there are at least four political principals. In this multiple-principal-system there is no identifiable hegemon.[190] E.U.

187. *See* Case C-396/06, *Kramme*, 2006 O.J. (C 294) 52 at ¶ 16 (noting that although EASA's airworthiness requirements are not directly at issue, they are nevertheless relevant); Commission Regulation 2042/2003, pmbl., Annex, 2003 O.J. (L 315) 1, 4 (establishing common technical requirements for ensuring the continuing airworthiness of aircraft).

188. *See* Consolidated Treaty, *supra* note 146, art. 230 (allowing that "[a]ny natural or legal person may, under the same conditions, institute proceedings against a decision addressed to that person or against a decision which, although in the form of a regulation or a decision addressed to another person, is of direct and individual concern to the former").

189. *See* Albertina Albors-Llorens, *The Standing of Private Parties to Challenge Community Measures: Has the European Court Missed the Boat*, 62 CAMBRIDGE L.J. 72, 72 (2003) (providing an overview on the standing requirements of the ECJ and noting that in the past forty years "private parties have rarely been able to surmount this formidable admissibility barrier when challenging Community acts").

190. *See* J.H.H. Weiler, *The Transformation of Europe*, 100 YALE L.J. 2403, 2413-31 (1991) (pointing out that the lacking hegemony of a single EU actor is of course not accidental but the perpetuation of basic features of European integration: balance and compromise, larger and smaller states acting on a level of

agencies are horizontally held accountable to the Council, the Commission, the European Parliament, and the Member States, with additional accountability to the Court of Auditors and the European Ombudsman. Structurally, the political accountability[191] of the E.U. administration differs in a significant point from the hierarchical political accountability that is still prevalent in most Member State administrations.[192] Other than on the national level, there is no responsible Minister to be held politically accountable.[193]

Of particular interest is the increasing role of the European Parliament, which plays an ever more active part in crafting and controlling the agencies. A first serious instrument to shape the E.U. agencies accountability profile is the increasing lawmaking power of the European Parliament, which still does not include initiative powers, but guarantees relevant participation and veto rights in the process of setting up the agency. As one leading European law scholar puts it: "The greater the specification of agency objectives and criteria for attainment, the greater the control exercised over

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relative equality).

191. *See* RICHARD MULGAN, HOLDING POWER TO ACCOUNT: ACCOUNTABILITY IN MODERN DEMOCRACIES 36-74 (2003) (opining that the capacity of governments to severely infringe citizens' rights justifies correspondingly strict guarantees of government accountability); *see also* Jody Freeman, *Extending Public Accountability Through Privatization: From Public Law to Publicization*, *in* PUBLIC ACCOUNTABILITY: DESIGNS, DILEMMAS AND EXPERIENCES, *supra* note 123, at 83, 84 (arguing that political accountability is reaching into the private sphere as the price private actors pay for "access to lucrative opportunities to deliver goods and services").

192. *See* MAX WEBER, ECONOMY AND SOCIETY: AN OUTLINE OF INTERPRETIVE SOCIOLOGY 987-89 (Guenther Roth & Claus Wittich eds., Univ. of California Press 1978) (1968) (positing that bureaucratized administrations are indestructible and virtually impervious to revolution); A. V. DICEY, INTRODUCTION TO THE STUDY OF THE LAW OF THE CONSTITUTION 195, 308-35 (5th ed. Gaunt, Inc. 2004) (1897) (noting that *droit administratif* is the prevalent system in most continental countries and contrasting it with the English administrative system). *But see* Bovens, *supra* note 108, at 110 (observing that many countries are starting to move away from such hierarchical accountability systems by establishing independent offices of ombudsman, auditors, and inspectors).

193. *See* Veit Mehde, *Die Ministerverantwortlichkeit nach dem Grundgesetz*, 116 DEUTSCHES VERWALTUNGSBLATT 13 (2001) (comparing Britain, France, Germany and Italy); Bovens, *supra* note 108, at 109 (noting that "it is still being debated whether individual European commissioners are accountable for civil servants working in the commission"). Instead, there is only "a *collective* accountability of the commission as a whole to the European Parliament." *Id.*

agency choices by the legislature."[194] Moreover the Parliament put significant legislative efforts into expanding the transparency requirements for financial management. Particularly important is the 2002 Financial Regulation, which extended the transparency requirements in budgetary procedures and financial management,[195] and also provided the European Parliament with the power to give discharge to the agencies for the implementation of their annual budgets.[196] Furthermore, the Parliament shares with the Council the budgetary power—and the "power of the purse" is indeed one of the most effective ex ante accountability tools.[197] With regard to ex post accountability, there are no general rules that would allow either the European Parliament or the National Parliaments to scrutinize an agency's activities. However, the Parliament has the right to summon the head of some of the more recently founded agencies, such as the EASA.[198] In addition, the European Parliament uses more informal instruments, such as inter-institutional agreements, in order to supplement accountability arrangements for agencies.[199]

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194. *See* CRAIG, *supra* note 3, at 169 (pointing out, conversely, that vague injunctions as to what the agency is intended to do will leave more power to the agency).

195. For an overview on Council Regulation 1605/2002; *see* Vos, *Agencies and the European Union*, *supra* note 55, at 138; Craig, *supra* note 102, at 108-10 and passim.

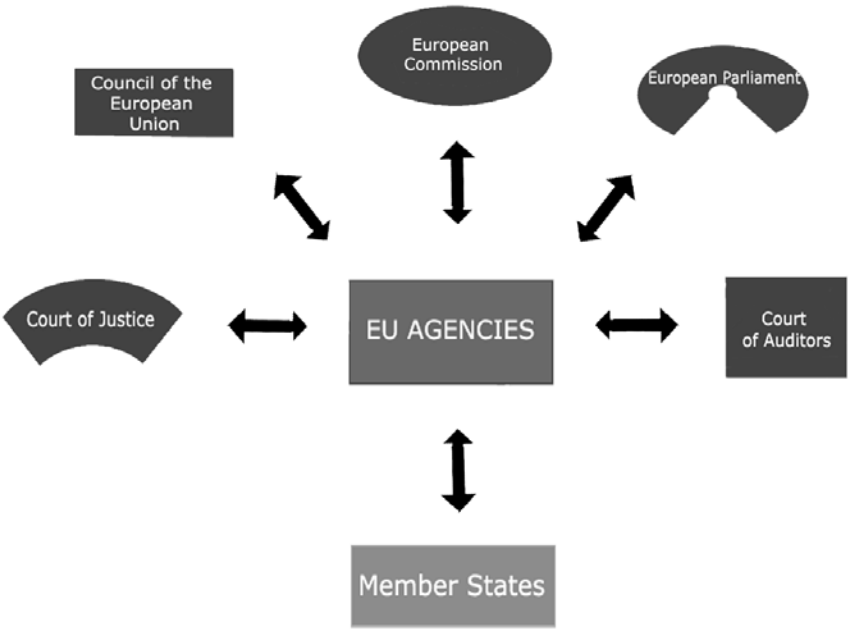
196. *See* Council Regulation 1605/2002, art. 185 no. 2 (ruling that discharge for the implementation of the budgets of bodies set up by the Communities and having legal personality, which actually receive grants charged to the budget, shall be given by the European Parliament on the recommendation of the Council).

197. The procedure for adoption of the budget is laid down in Art. 272 TEC; Ellen Vos, *European Administrative Reform and Agencies* 13 (Robert Schuman Centre for Advanced Studies EUI Working Papers, RSC No. 2000/51 2000), *available at* http://www.eui.eu/RSCAS/WP-Texts/00_51.pdf (pointing out that the Parliament has significant power due to its ability to determine Community subsidies and agencies' budgets).

198. *See* Parliament & Council Regulation 216/2008, *supra* note 66, art. 38(2) (empowering the Parliament to invite EASA's Executive Director "to report on the carrying out of his/her tasks").

199. *See, e.g.*, Interinstitutional Agreement Between the European Parliament, the Council and the Commission on Budgetary Discipline and Sound Financial Management, 2006 O.J. (C 139) 1 (EC); Curtin, *supra* note 25, at 532 (arguing that the European Parliament has used its role as co-legislator of the Financial Regulation to expand transparency in budgetary procedures); *see also* Catherine Moury, *Explaining the European Parliament's Right to Appoint and Invest the Commission*, 20 W. EUR. POL. 367, 370 (2007) (arguing that Parliament has been trying to increase its power by using its advantageous bargaining position in

FIGURE 3: THE MULTIPLE-PRINCIPAL-SYSTEM OF E.U. AGENCY ADMINISTRATION (SIMPLIFIED)



The arrows mark the accountability relations of the EU agencies to their various principals, including the Council of the European Union, the Commission, the European Parliament, the European Court of Justice, the Court of Auditors, and the EU Member States.

The European Ombudsman also counts into the forums established to enhance political accountability, although this institution is largely lacking formal powers to coerce public actors into compliance.[200] Yet the European Ombudsman office deals with accountability of E.U. agencies too. The annual report of 2005 revealed that the European Ombudsman office subjected EASA to inquiries in one case, and subjected EMEA to inquiries in three cases.[201] In 2006, the

appointing members of the Commission).

200. *See* Bovens, *supra* note 108, at 116 (asserting that most administrative accountability relations, such as ombudsman, are effective only if parliaments pay attention to them).

201. *See* THE EUROPEAN OMBUDSMAN, ANNUAL REPORT 2005 160 (2006), http://www.ombudsman.europa.eu/report05/pdf/en/rap05_en.pdf (revealing that in 2005 the European Ombudsman dealt with 627 inquiries).

Ombudsman helped to find a friendly solution for an EASA employee who was rejected after serving six months in a probationary period.[202] Moreover, the Ombudsman engages in standard setting for accountability structures and processes.[203] For example, in 2000 the Ombudsman issued the "European Code of Good Administrative Behaviour" and urged the European Union institutions to sign up.[204] Indeed, in 2001 the EMEA became one of the (few) E.U. agencies to apply the Code.[205]

The accountability relation of each agency to the European Court of Auditors includes a broad range of financial requirements. The Court of Auditors publishes detailed reports on the annual agency accounts, along with a statement of the agency in the Official Journal of the European Union.[206] For example, the Court of Auditor's report

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202. *See* THE EUROPEAN OMBUDSMAN, ANNUAL REPORT 2006 74 (2007), http://ombudsman.europa.eu/report06/pdf/en/rap06_en.pdf (holding the EASA provided incomplete information with regard to the complainant's installation allowances and that, although case law provides that officials are presumed to know their rights, Community institutions still may not provide misleading information).

203. *See* Carol Harlow & Richard Rawlings, *Promoting Accountability in Multi-level Governance: A Network Approach* 23 (European Governance Papers, No. C-06-02, 2006), *available at* http://www.connex-network.org/eurogov/pdf/egp-connex-C-06-02.pdf (describing the European Ombudsman as performing "fire-watching" and "fire-fighting" functions, as illustrated by the Ombudsman's use of his *European Code of Good Administrative Behavior* as the benchmark for maladministration in individual cases).

204. *See generally* THE EUROPEAN OMBUDSMAN, THE EUROPEAN CODE OF GOOD ADMINISTRATION BEHAVIOUR 6-9 (2005), http://ombudsman.europa.eu/code/pdf/en/code2005_en.pdf (emphasizing citizens' rights to good administration and noting that the Ombudsman uses the Code in its investigations of alleged maladministration cases).

205. *See* Commission Regulation 216/2008, *supra* note 66, art. 58(1) (subjecting the agency to the fundamentally important Council regulation 1049/2001 that authorizes public access to the EU institutions' documents). The Regulation also allows individuals to file a complaint with the European Ombudsman office if EASA does not timely reply to a request for information. *Id.* pmbl., ¶ 36. Additionally, the Regulation entitles any natural or legal person to write to the EASA and to receive an answer in her or his own language. *Id.* art. 58(3).

206. *See*, *e.g., Court of Auditors Report on the Annual Accounts of the European Aviation Safety Agency for the Financial Year 2005 Together with the Agency's Replies*, ¶¶ 1-10, 2006 O.J. (C 312) 6 (finding EASA's accounts reliable and listing problematic issues); *see also Court of Auditors Report on the Annual Accounts of the European Medicines Agency for the Financial Year 2005 Together with the Agency's Replies*, ¶ 5, 2006 O.J. (C 312) 12 [hereinafter *Annual Accounts of the*

on the European Medicines Agency for 2005 included the final budget (111.8 million Euro), the total staff (371.5).[207] In the area of Medicinal Products for Human Use, the ECA reported the applications for marketing authorizations for (forty-three, with twenty-four receiving favorable opinions), the average evaluation time (203 days), the opinions after authorization (1148), acts of pharmacovigilance (91,565 reports), scientific opinions (135) and procedures for mutual recognition (8451).[208] Similarly, accounts were given for the agency's activities toward Medicinal Products for Veterinary Use and Orphan Medicinal Products.[209] Generally the concession of some financial flexibility is acknowledged as a crucial precondition for the concept of regulatory agencies. For example, the EASA Basic Regulation states: "In order to guarantee the full autonomy and independence of the Agency, it should be granted an autonomous budget whose revenue comes essentially from a contribution from the Community and from fees paid by the users of the system."[210] Yet in reaction to the Commission's credibility and corruption crisis of the mid-1990s, financial accountability became a major concern for many E.U. actors. The E.U. adopted several overall financial regulatory regimes, and the system of financial accountability has been unified for all E.U. agencies in 2002.[211] The E.U. established a range of budgetary principles, including those of unity, budget accuracy, annuality, equilibrium, universality, specification, sound financial management, and transparency.[212] Financial control is exercised ex ante to set up and decide the annual

European Medicines Agency] (indicating EMEA passed the audit).

207. *Annual Accounts of the European Medicines Agency*, *supra* note 206, at tbls. 1-2.

208. *Id.* tbl. 1.

209. *Id.*

210. Parliament & Council Regulation 216/2008, *supra* note 66, pmbl., ¶ 27.

211. *See* Council Regulation 1605/2002, *supra* note 196, arts. 1-5 (requiring all revenues and expenditures to be entered into the budget); s*ee also* Commission Regulation 2342/2002, art. 1, 2002 O.J. (L 357) 1, 7 (laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002); Commission Regulation 478/2007, pmbl., 2007 O.J. (L 111) 13 (amending Regulation 2342/2002).

212. Council Regulation 1605/2002, *supra* note 197, art. 3; *see* Matthew Flinders, *Distributed Public Governance in the European Union*, 11 J. EUR. PUB. POL'Y 520, 536 (2004) (asserting that because agencies fall under the so-called non-compulsory part of the European Community budget, the European Parliament can impose strict accountability requirements).

budget.[213] In a gradual process, the agency provides a proposal for next year's budget that serves as basis for an overall draft of the Commission.[214] The overall E.U. budget is set up by the European Council and the European Parliament as budget authority.[215] The ex post control mechanisms are supported by the agencies through the submission of detailed annual accounts, including financial statements such as the balance sheet, economic outturn account, cash flow statement, and relevant annexes, which supplement the information contained in the financial statements and the report of the implementation of the budget.[216] The European Parliament is also entitled with financial control competencies, which are of a rather political nature. Art. 49 (4) of the EASA Basic Regulation rules that the European Parliament, acting on a recommendation from the Council, shall give a discharge to the Executive Director of the Agency in respect of the budget. Moreover, both EMEA and EASA are also subject to the jurisdiction of the European Anti-Fraud Office (OLAF), which is an independent authority within the Commission, charged to fight internal and external corruption.[217]

C. INTERNAL AND EXTERNAL ACCOUNTABILITY MECHANISMS

As described in the preceding paragraphs, the European agencies are accountable to a multitude of principals. The identified responsibility and control relations could also be understood in terms of internal and external accountability mechanisms.[218] In this

213. *See* Ellen Vos, *Reforming the European Commission: What Role to Play for EU Agencies?*, 37 COMMON MKT. L. REV. 1113, 1126-27 (2000) (pointing out that Parliament has not hesitated to exercise its ex ante control of agencies budgets "in the name of transparency and accountability").

214. Consolidated Treaty, *supra* note 146, art. 272.

215. *Id.*

216. *See, e.g.*, EUROPEAN MEDICINES AGENCY, ANNUAL ACCOUNTS FINANCIAL YEAR 2006 3 (2007), www.emea.europa.eu/pdfs/general/direct/emeaar/EMEA_Annual_Report_2006_full.pdf (asserting that for a public entity such as EMEA, the purpose of the financial report is to provide information useful for decision-making and to demonstrate the agency's responsible handling of resources entrusted to it).

217. *See, e.g.,* Parliament & Council Regulation 216/2008, *supra* note 66, art. 61 (maintaining that the provisions of Regulation (EC) No 1073/1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) apply to EASA without restriction); Parliament & Council Regulation 726/2004, *supra* note 95, art. 69 (requiring unconditional submission to OLAF's authority).

218. *Cf.* Kalypso Nicolaidis & Gregory Shaffer, *Transnational Mutual*

perspective, the Member States are the primary external principal. All the other entities are located within the E.U. institutions, and thus are internal principals. The role of the Member States is probably the most remarkable and genuinely supranational feature in the E.U. agency accountability regime. They exercise controls not only through their representatives in the E.U. institutions and committees, but also in a quasi horizontal accountability mode through political mechanisms on the national level, such as public hearings held by the national parliaments to scrutinize the work of European Agencies.[219]

1. Management Board and Committees

A particularly powerful accountability tool in the hands of the Member States is the management board of either agency. The institutional designs of both the EMEA and EASA guarantee one seat to a nominee of each Member State.[220] The same mechanism of one nominee per Member State is applied to the composition of the EMEA Committees for Medicinal Products for Human Use and Medicinal Product for Veterinary Use.[221] The extent to which Member State representatives actually act as agents of their nations, rather than as agents of the European Community, is not always clear. The status of the individual members in terms of independence or constraints issued by the Member State is not uniform. Whereas the basic regulations of agencies such as the EMEA provide for certain independence,[222] similar provisions are lacking in the EASA

Recognition Regimes: Governance Without Global Government, 68 L. & CONTEMP. PROBS. 263, 299-301 (2005) (positing that in an economically integrated world, in which regulatory decisions of national authorities can affect foreign entities, internal accountability refers to accountability of national authorities to their constituents, whereas external accountability refers to accountability of national authorities to outsiders).

219. *See* HOUSE OF COMMONS TRANSPORT COMMITTEE, THE WORK OF THE CIVIL AVIATION AUTHORITY, 2005-06, H.C. 809, at 13-20, *available at* http://www.publications.parliament.uk/pa/cm200506/cmselect/cmtran/809/809.pdf (assessing the working relationship between the U.K.'s Civil Aviation Authority and EASA).

220. Parliament & Council Regulation 726/2004, *supra* note 95, art. 65; Parliament & Council Regulation 216/2008, *supra* note 66, art. 34.

221. Parliament & Council Regulation 726/2004, *supra* note 95, art. 61(1).

222. *See id.* art. 61(6) (stating that "Member States shall refrain from giving committee members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibility of the Agency"). The

basic regulation. Thus in the case of EASA, the Member State representatives appear to be subject to directives of either national government. Hence the crucial level of reference for the management board representatives is either national state.[223] All Member States are represented on the management boards of both the EMEA and EASA. The partially obstructing effects of this design caused the Commission to press for a general reform of the management boards. The Commission championed a more professional and scientific model favoring professional experts instead of nation state representatives.[224] Yet these ideas were dismissed in the 2004 EMEA reform process.[225]

2. Network Accountability

Another informal mode of horizontal accountability results from the day-to-day information exchange between the European agency and the relevant authorities on the national scale ("hub and spoke model").[226] For example, the EASA regulation includes a provision for an information network between the agency, the commission, and national aviation authorities.[227] The EASA can enlist the help of

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Regulation also sets out a mandatory deference standard which purports that "members of the committees and experts responsible for evaluating medicinal products shall rely on the scientific evaluation and resources." *Id.*

223. *See* RIEDEL, *supra* note 126, at 70.

224. *See Communication from the Commission, The Operating Framework for the European Regulatory Agencies*, *supra* note 82, at 9 (criticizing the status quo and arguing for smaller boards with at least some members nominated by interested parties and some national executives with experience in managing agencies); *see also Draft Interinstitutional Agreement*, *supra* note 89, art. 11(5) (arguing that Member States should be allowed to appoint their representatives to the boards of only those agencies that exercise executive powers in those States).

225. *See* Parliament & Council Regulation 726/2004, *supra* note 95, art. 1 (laying down Community procedures for the authorization and supervision of medicines for human and veterinary use and establishing a European Medicines Agency).

226. *See* Hofmann & Türk, *supra* note 23, at 87 (noting that European agencies integrate national administrative bodies and authorities into their operation, usually through the creation of networks to facilitate cooperation and exchange of expertise).

227. *See* Parliament & Council Regulation 216/2008, *supra* note 66, art. 15(1) (stating that "[t]he Commission, the Agency, and the national aviation authorities shall exchange any information available to them in the context of the application of [the EASA Basic] Regulation and its implementing rules").

national aviation authorities in the issuing of airworthiness certificates, drawing on their expertise in this area, and can work with such national authorities for investigation and enforcement.[228] In the case of EASA, the necessity of networking with the national agencies is evident: The transnational character of the regulatory object requires the flow of information between relevant players at national, Community, and international levels. In addition, practical needs of inspection and enforcement argue for cooperation. The European pharmaceutical regulation relies also on a network of national and European authorities. The EMEA provides for the network's technological framework through the management of EUDRANET, a human and veterinary pharmaceuticals telecommunication network.[229] EUDRANET is intended to provide a platform for communication, information exchange, and cooperation for authorities, policy makers, scientific experts, and representatives of pharmaceutical businesses.[230]

3. The Practice of Horizontal Accountability

The United Kingdom provided a most recent and fascinating practical example of horizontal accountability mode involving the European Aviation Safety Agency, when the Transport Committee[231] of the British Parliament explored the organization and work practice of the EASA.[232] The Parliamentary Committee summoned the head

228. *See id*. arts. 10, 20, 52(1)(a) (providing for the development of certification specifications employing the expertise of national aviation authorities, for national authorities to conduct investigations of the undertakings in application of specific Articles of the regulation, and for Member States, the Commission, and the EASA to cooperate to ensure compliance and enforcement).

229. *See* IDABC, Eudranet: European Telecommunication Network in Pharmaceuticals, http://ec.europa.eu/idabc/en/document/2291 (last visited Oct. 12, 2008) (explaining the management, objectives, and functioning of EUDRANET).

230. *Id.*

231. *See generally* HOUSE OF COMMONS, STANDING ORDERS OF THE HOUSE OF COMMONS – PUBLIC BUSINESS 2007, at 150-53 (Nov. 19, 2007), http://www.publications.parliament.uk/pa/cm200708/cmstords/105/105.pdf (setting forth that the Transport Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department for Transport and its associated public bodies). The Committee is one of the departmental select committees, the powers of which are set out in House of Commons Standing Orders, principally in Standing Order No. 152. *Id.*

232. *See* HOUSE OF COMMONS TRANSPORT COMMITTEE, THE WORK OF THE

of the national British Civil Aviation Authority—widely acknowledged as a worldwide model authority in its field[233]—representatives of pilots and aircraft engineers organizations, and several experts from the social sciences. The Parliamentary Committee was not satisfied with the performance of the EASA, decrying the fact that the speed of rule-making had slowed down since it was transferred from the national British to the European level.[234] In the highly technical and evolutionary field of aircraft safety, this caused worries about keeping pace with the necessary standards.[235] Other concerns were related to a lack of responsibility among the EASA staff, the personal choices of the management board, as well as the deficiencies in the personal and technical resources that EASA needed to manage its current tasks.[236]

As a conclusion of its assessment, the British Parliamentary Committee stated in drastic words:

> It is with dismay that we have learnt of the chaotic state of the European Aviation Safety Agency (EASA), which at this time is not able to fulfill its declared purpose. EASA is an accident waiting to happen—if its problems are left unchecked, we believe it has the potential to put aviation safety in the UK and the rest of Europe at risk at some point in the future.[237]

The Committee also warned against transferring further powers from the national level to the E.U. agency, stating that "[t]he United Kingdom cannot and must not transfer any further powers from the CAA to EASA until the Government is assured that the serious problems of governance, management and resources at EASA have been resolved," expecting assurances from the Minister on the topic.[238] The Parliamentary Committee urged the British government to work towards resolving the operational problems of EASA. Faced

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CIVIL AVIATION AUTHORITY, *supra* note 219, at 13-22 (examining the background of the EASA, its current effectiveness, and the operational problems with which it is faced).

233. *See id.* at 23-25 (detailing CAA's good performance review marks).
234. *Id.* at 17.
235. *See id.* (noting that the delays in regulation threaten aviation safety).
236. *Id.* at 15.
237. *Id.* at 16.
238. *Id.*

with these charges, the British government took various actions. About six months later, the British government claimed to have "played a leading role in improving the performance of the EASA" and announced that it would "continue to take steps to ensure that the Agency is firmly established as a properly resourced and high performing safety regulator."[239] The United Kingdom pointed especially to the influential work of their member on the EASA Management Board to improve manpower, planning, and risk management.[240] In addition, the British government stressed the close informational and personal exchange of the E.U. agency and its national pendant.[241] Along these lines, the French Parliament recently started its own extended inquiry into the entire European Agency system.[242] Its report questioned the overall performance of the agency system, and in particular its legal framework.[243] Moreover, the French urged the European Commission to provide a thorough evaluation on the agency system. The agencies were urged to make information on their work available in the languages of all Member States.[244]

III. FUTURE PROSPECTS

With regard to future prospects, there are several fascinating issues likely to appear on the agenda. In particular there is the 2007 European Treaty of Lisbon, which provides for a significant

239. HOUSE OF COMMONS TRANSPORT COMMITTEE, THE WORK OF THE CIVIL AVIATION AUTHORITY: GOVERNMENT RESPONSE TO THE COMMITTEE'S THIRTEENTH REPORT OF SESSION 2005-06, 2006-07, H.C. 371, at 3 (expressing the British government's responses to the Transport Committee report, and the government's belief that the EASA is now on track to assume the additional responsibilities envisioned for it under upcoming amendments to Community legislation).

240. *Id.* at 5.

241. *See id*. (noting how the CAA's Safety Regulation Group keeps its staff informed on EASA's transitional phases by utilizing multiple communication formats, including management briefings that facilitate the structured diffusion of information throughout each part of the organization).

242. Rapport D'Information Déposé par la Délégation de l'Assemblée Nationale pour l'Union Européenne sur les Agences Européennes par M. Christian Philip, Député, COM (2005) 59 final, COM (2005) 190 final, COM (2005) 280 final (May 3, 2006).

243. *Id.*

244. *See id.* at 85.

constitutionalization of E.U. agencies. Moreover, the Treaty shows an emerging trend toward global licensing cooperation between agencies of the E.U. and other jurisdictions.

A. THE E.U. TREATY OF LISBON (2007)

On December 13, 2007 the heads of the E.U. Member States agreed upon the Treaty of Lisbon[245] in order to replace the collapsed project of a European Constitutional Treaty. The new reform treaty provides for a multitude of institutional, substantive and procedural amendments to the Treaties on the European Union and the European Community.[246] Procedurally, the Treaty of Lisbon primarily modifies the decision-making processes of the European Union in order to cope with the new reality of twenty-seven E.U. Member States in a political entity which at the outset included only six.[247] The Treaty of Lisbon for the first time provides for a constitutional framework of European administration, including rules for the delegation of rule-making power from the Council to the Commission,[248] and "administrative cooperation" among the Union and the Member States so as to "improve their administrative capacity to implement Union law."[249] It also provides indirectly for the constitutionalization

245. *See generally* Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Community, Dec. 13, 2007, 2007 O.J. (C 306) 1 [hereinafter Treaty of Lisbon].

246. *See id*. at 10 (stating that the Member States have agreed upon the "Amendments to the Treaty on European Union and to the Treaty Establishing the European Community").

247. *See* Margot Wallstrom, Vice President of the European Comm'n, Speech to the National Forum on Europe (Feb. 28, 2008), http://ec.europa.eu/ireland/press_office/speeches-press_releases/wallstromforumspeech_en.htm (observing "[y]ou can't run a Union of 27 with machinery designed for a Community of six.").

248. *See* Treaty of Lisbon, *supra* note 245, art. 2, ¶ 236 (resembling the *Meroni* doctrine in stating that the Council "may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act"). The Treaty further specifies that "[t]he objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts." *Id.* Furthermore, the Treaty emphasizes that "[t]he essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power." *Id.*

249. *Id*. art. 2, ¶ 150 (suggesting the facilitation of the exchange of information and of civil servants, in addition to supporting training schemes, as potential actions to foster this improvement).

of E.U. agencies. Although the agencies are not included in the catalogue of the Union's institutions,[250] various new provisions regulate the agencies' actions. The adoption of the proposed reforms would enhance and unify the accountability regimes of E.U. agencies significantly. Presumably the most important practical aspect is the explicit and universal inclusion of the actions of E.U. agencies under the jurisdiction of the European Courts. The proposed amendment states that the European Court of Justice ". . . shall . . . review the legality of acts of bodies, offices or agencies of the Union intended to produce legal effects vis-à-vis third parties."[251] Standing is to be granted to "[a]ny natural or legal person . . . against an act addressed to that person or which is of direct or individual concern to them, and against a regulatory act which is of direct concern to them and does not entail implementing measures."[252] Once the Treaty of Lisbon comes into effect, it would also tremendously enhance the publicity of agency actions. It proposes not only that "[i]n order to promote good governance and ensure the participation of civil society, the Union institutions, bodies, offices and agencies shall conduct their work as openly as possible," but also grants citizens of the Union a right of access to "documents of the Union institutions, bodies, offices, and agencies, whatever their medium."[253]

The Treaty of Lisbon was originally supposed to enter into force on January 1, 2009—provided that all twenty-seven E.U. Member States would have ratified the document by that point. Contrary to the 2004 draft for a European Constitutional Treaty, which in most states had to overcome the barrier of a referendum, the framers of the Treaty of Lisbon assumed that the ratification would not require referendums, but only qualified majority approvals in the national legislatures. European officials justify this assumption by declaring that now there is not a Constitution but a mere reform treaty at stake.

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250. *See id*. art. 1, ¶ 14 (enumerating the Union's institutions, specifically stating that the "Union's institutions shall be: the European Parliament, the European Council, the Council, the European Commission, the Court of Justice of the European Union, the European Central Bank, the Court of Auditors").

251. *Id*. art. 2, ¶ 214(a) (amending Article 230(1) of the Treaty Establishing the European Community).

252. *Id*. art. 2, ¶ 214(c).

253. *Id*. art. 2, ¶ 28(a), (b) (amending article 255 of the Treaty Establishing the European Community, which presently grants E.U. citizens access only to documents of the European Parliament, Council, and Commission).

Thus, so the argument goes, the same parliamentary ratification procedure applies as it did in the context of earlier major reform treaties, such as the Single European Act of 1986, and the Maastricht Treaty of 1992 establishing the Economic and Monetary Union.[254] All major countries followed the course of the Treaty in the first phase of ratification. Even the French, whose negative referendum in 2005 stopped the Constitutional Treaty, have already approved the Treaty of Lisbon by a parliamentary majority in the French National Assembly.[255] Similarly in Britain, where the political forces in favor of a referendum are very strong, the House of Commons has also already voted against a referendum and for the parliamentary ratification of the Treaty of Lisbon.[256] The British judiciary upheld the Parliament centered course of the British government, and turned down a lawsuit which was brought in favor of a referendum.[257]

However, the new avenue to European institutional reform has not remained unchallenged. Opponents of the recent shift in the mode of constitutional change point to the broad convergences of the Treaty of Lisbon and the failed draft for a Constitutional Treaty.[258] The

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254. *See generally* Vaughne Miller, *European Union (Amendment) Bill, Bill 48 of 2007-08* (House of Commons Library, Research Paper 08/03, 2008), http://www.parliament.uk/commons/lib/research/rp2008/rp08-003.pdf (discussing the treaty ratification process in the UK and the ratification procedures in other Member States).

255. *See French Parliament Adopts Lisbon Treaty*, AFP, Feb. 8, 2008, http://www.france24.com/en/20080208-french-parliament-adopts-lisbon-treaty-france-eu (documenting the resounding approval of the Lisbon Treaty by the French National Assembly and Senate).

256. *See MPs Reject EU Treaty Referendum*, BBC NEWS, Mar. 5, 2008, http://newsvote.bbe.co.uk./mpapps/pagetools/print/news.bbc.co.uk/1/hi/uk_politics/7277644.stm (describing how the House of Commons, by 311 votes to 248 votes, turned down the proposal to hold a UK-wide referendum concerning whether to ratify the Lisbon Treaty).

257. The Queen v. Office of the Prime Minister, [2008] EWHC (Admin) 1409, ¶¶ 57-59 (finding the ratification process through a parliamentary vote lawful and referendum unnecessary).

258. *See, e.g.*, *La Bôite à Outils du Traité de Lisbonne*, LE MONDE (France), Oct. 27, 2007, at 21 (publishing an open letter by Valéry Giscard d'Estaing, the former French President who had chaired the Convention that had framed the abandoned Treaty for a European Constitution, where Giscard claims that the Treaty of Lisbon is substantially equivalent to the original Treaty for a European Constitution (En Traité européen "les outils sont exactement les mêmes, seul l'ordre a été changé dans la boîte à outils . . . 'les innovations permettant d'améliorer le fonctionnement de l'Europe sont conservées ' dans le nouveau traité

majority vote in the Republic of Ireland, which so far has been the only Member State to proceed with a referendum, rejected the Treaty.[259] With the Irish rejection, the ratification process came to a standstill. However, in light of the huge importance of the institutional reform, and in order to cope with the new reality of a political community including twenty-seven Member States, the Council and the Commission are making huge efforts to solve the crisis arising from the Irish rejection.[260] Due to the broad coalition in favor of institutional reform, the Treaty of Lisbon is still quite likely to come into existence as proposed.[261] After E.U. leaders agreed to a series of concessions, Ireland is expected to have a second referendum on the Lisbon Treaty during the fall of 2009.[262]

B. GLOBAL LICENSING COOPERATION

Another important development is the increase of global licensing cooperation. Forums and instruments are particularly well developed in the work of the EASA. In this subject matter, international cooperation makes perfect sense because airplane licensing and

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institutionnel")). This is probably the strongest argument for the necessity of referendums on the Treaty of Lisbon instead of legislative ratifications.

259. *See* IR. CONST., 1937, arts. 46-47 (requiring that ratification of an amendment to the Constitution of Ireland be effected by referendum); *see also* Vaughne Miller, *The Treaty of Lisbon: An Uncertain Future* 10 (House of Commons Library, Research Paper 08/66, 2008), *available at* http://www.parliament.uk/commons/lib/research/rp2008/rp08-066.pdf (noting that the reason for the referendum was that any "'significant' amendment to EU Treaties requires an amendment to the Irish Constitution").

260. *See* Press Release, European Parliament, Sarkozy to the European Parliament: "Europe Cannot be Condemned to Inaction" (July 9, 2008), http://www.europarl.europa.eu/sides/getDoc.do?language=EN&type=IM-PRESS&reference=20080709IPR33856 (discussing the Irish "no-vote" and the current EU Presidency's opinions regarding the importance of the Treaty of Lisbon for the continued enlargement of Europe).

261. *See* Miller, *supra* note 254, at 59-70 (reporting that twenty-four Member States have already ratified the treaty with the remaining two in the process of ratifying it). *Cf.* Europa – Treaty of Lisbon, Taking Europe into the 21st Century, http://europa.eu/lisbon_treaty/index_en.htm (last visited Oct. 12, 2008) (updating the status of approval of the Treaty of Lisbon, with Spain's and Italy's endorsements of the Treaty in July 2008).

262. *See* BBC *Ireland PM confirms EU vote plan*, BBC NEWS, Dec. 12, 2008, http://news.bbc.co.uk/2/hi/europe/7779854.stm (reporting that Ireland's Prime Minister Brian Cowen said that on the basis of concessions agreed at to an E.U. summit in Brussels, he was prepared to go back to the Irish people next year).

certification is per se a regulatory subject of global dimensions, equally relevant for each authority in the jurisdiction that the specific airplane is intended to be employed. The EASA distinguished in its 2008 work program three pillars of its activities in "[n]etworking and broadening partnership with civil aviation authorities across the world".[263] These are (1) the "reciprocal acceptance of certification findings with fit and able regulatory partners," (2) the "building-up of the capabilities of less developed future regulatory partners," and (3) "involvement in multilateral activities related to civil aviation safety and environmental compatibility regulation."[264] In particular the EASA and the American Federal Aviation Administration (FAA) are already cooperating on several levels. EASA and the FAA established a "mutual concept of 'validation' . . . the recognition and acceptance of each other's type certificates without having to go through the entire certification process."[265] The EASA Executive Director illustrates this process by the example that while the EASA "is the primary certification authority for the new Airbus A380, the FAA will 'validate' the EASA type-certificate for the U.S., and vice versa for the Boeing 787 in Europe."[266] Article 9 of the EASA-Basic regulation provides a normative basis for the acceptance of a third-country approval.[267] The EASA and its American counterpart are constantly exchanging guidance material and holding common

263. EUROPEAN AVIATION SAFETY AGENCY, 2008 WORK PROGRAMME 26 (2007) (maintaining that its activities in this domain are crucial activities of the EASA).

264. *Id.*

265. Philip Butterworth-Hayes, *With Patrick Goudou*, AEROSPACE AMERICA, June 2006, at 10 (interviewing EASA Executive Director Patrick Goudou regarding topics ranging from the interface between EASA and national safety agencies to how EASA will work with the FAA on joint certification).

266. *Id.*

267. *See, e.g.*, Parliament & Council Regulation 216/2008, *supra* note 66, art. 9 (allowing non-E.U. airlines to operate within the E.U. as long as they comply with standards promulgated by the International Civil Aviation Organization); *see also* Executive Director of the European Aviation Safety Agency Decision No. 001/2007/C, Mar. 9, 2007, art. 1 (providing a recent application of this principle, whereby the Decision amends Article 3 of Decision No. 2004/04/CF of 10 December 2004 on the acceptance of certification findings made by the Federal Aviation Administration (FAA) for products designed in the United States by replacing the words "minor repair design of a product for which the United States of America is State of design" with the words "repair design, not related to a critical part, of a product").

workshops.[268] Several times, the EASA and the FAA published their positive approval in common press conferences.[269] One could identify a similar pattern of transatlantic cooperation for the European Medicines Agency, which also seeks close cooperation with its American counterpart, the U.S. Food and Drug Administration (FDA).[270] In terms of administrative accountability, the fascinating emergence of global licensing cooperation among agencies on different continents is far from unproblematic. The puzzling question is how an adequate level of accountability could be ensured in cases where a particular rule or decision is only formally issued by a European agency, but pre-determined or at least heavily influenced by a foreign authority. So far, there has been no major academic discussion on this issue of global administrative law; however, the identification of the problem will hopefully spur further scholarly inquiries.[271]

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268. *See, e.g.*, EU/US International Aviation Safety Conference 2007, http://www.easa.europa.eu/conf2007/ (last visited Oct. 12, 2008) (reporting on this annual conference's success as a major forum on aviation safety and noting that EASA and FAA are co-chairing it, as usual). *See generally* Motion for a Resolution to Wind up the Debate on the Statement by the Commission Pursuant to Rule 103(2) of the Rules of Procedure, EUR. PARL. DOC. B6-0007 4 (2007) (acknowledging the cooperation of EASA and FAA in the area of safety).

269. *See*, *e.g.*, Press Release, Press and Public Diplomacy Delegation of the European Union, News Release No. 107/06: European Union Satisfied with EASA Safety Approval of Airbus A380 (Mar. 18, 2008), http://www.eurunion.org/eu/index.php?option=com_content&task=view&id=66&Itemid=58 (stating that, parallel to the EASA's type-certification, the U.S. Federal Aviation Administration (FAA) had issued its "validation" of the A380 certification for the U.S. market).

270. *See* European Medicines Agency, Transatlantic Cooperation in Pharmaceutical Regulation: Identifying Opportunities for Administrative Simplification, http://www.ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_11/tasw_joint_announcement.pdf (describing the outcomes of the Transatlantic Administrative Simplification Workshop in relation to identifying opportunities for administrative simplification through transatlantic cooperation); WORK PROGRAMME FOR THE EUROPEAN MEDICINES AGENCY 2005, 28 (2004) http://www.emea.europa.eu/pdfs/general/direct/emeawp/13835104en.pdf (designating as a key initiative that "[i]nteraction with the US Food and Drug Administration will be further developed through enhanced cooperation in the context of the confidentiality arrangements, e.g. in the fields of orphan medicinal products, scientific advice requests, new applications, pharmacovigilance, development of guidelines and the exchange of trainees and experts").

271. *See generally* Alfred C. Aman, Jr., Symposium: *Globalization, Accountability, and the Future of Administrative Law*, 8 IND. J. OF GLOBAL LEGAL STUD. 341 (2001) (describing the symposium articles' coverage of the issues of

Beyond the two novel trends of constitutionalization and global licensing cooperation, it is also likely that the E.U. will keep expanding the agency system both quantitatively and qualitatively. There are already new agencies under preparation, such as the European Institute for Gender Equality[272] and the European Electronic Communications Market Authority.[273] A further empowerment of agencies would surely require stronger and more coherent procedural constraints, particularly towards consultation and participation rights.[274] In this regard it will be helpful for the E.U. legislators to learn from the American experiences.[275] Some authors are already proposing a legislative framework for European

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administrative accountability and democratic deficits stemming from the rise of globalization); Daniel C. Esty, *Good Governance at the Supranational Scale: Globalizing Administrative Law*, 115 YALE L.J. 1490 (2006) (discussing some of the accountability problems arising in the context of global administrative law). *Cf.* Robert O. Keohane, *The Concept of Accountability in World Politics and the Use of Force*, 24 MICH. J. INT'L L. 1121 (2003) (developing a pluralistic theory of accountability, expounding eight accountability mechanisms found in democratic societies, and addressing the current practices of the Security Council from the perspective of accountability).

272. *See* Parliament & Council Regulation 1922/2006, art. 1, 2006 O.J. (L 403) 9, 9 (EC) (establishing the European Institute for Gender Equality and setting forth the Institute's objectives and associated tasks).

273. *See Commission Proposal for Regulation of the European Parliament and of the Council Establishing the European Electronic Communications Market Authority*, at 22, COM (2007) 699 final (Nov. 13, 2007) (proposing to establish the European Electronic Communications Market Authority and delineating its functions and role in the application of the regulatory framework).

274. *See* Richard B. Stewart, *U.S. Administrative Law: A Model for Global Administrative Law?*, 68 L. & CONTEMP. PROBS. 63, 63, 103-04 (2005) (examining the potential for U.S. administrative law to serve as a model in the development of a global administrative law, including mechanisms for increased participation).

275. *See generally* Damien Geradin, *The Development of European Regulatory Agencies: Lessons from the American Experience*, *in* REGULATION THROUGH AGENCIES IN THE EU, *supra* note 64, at 215 (examining the important development in the E.U.'s administrative structure associated with the considerable expansion of E.U. agencies and the related legal issues through systematic comparison with the U.S. regulatory system); Jerry L. Mashaw, *Reasoned Administration: The European Union, the United States, and the Project of Democratic Governance*, 76 GEO. WASH. L. REV. 99 (2007) (exploring the practice of administrative reason-giving in the European Union and the United States; and its important function in contributing to authentic democratic governance).

Union agencies similar to the U.S. Administrative Procedure Act of 1946.[276]

SUMMARY AND CONCLUSION

The system of European administration is undergoing a profound transformation. Most remarkably, since 1990 the European Union has established more than twenty-five administrative agencies to confront the challenges of the E.U. eastern enlargement, of increased responsibilities, and of economic globalization. The E.U. agencies do not operate as autonomous entities on the supranational scale, but rather are embedded into administrative networks of European and national authorities. Due to the lack of unifying provisions in the European Treaty framework, the accountability regimes are remarkably diverse. However, the case studies of this Article reveal not only a broad diversification of judicial review, participation, and transparency, but also a close connection between the formal powers of each agency and the applicable accountability mechanisms. The EASA, one of the first agencies vested with formal licensing powers, is identified as the agency with the most enhanced accountability features. One of the most idiosyncratic features of the E.U. agency system is the structural relationship between agents and principals. Whereas in the United States the President and Congress constitute the two major principals of federal agencies, the multiple-principal-system of European governance is at least fourfold. E.U. agencies are held accountable to the Council, the Commission and the European Parliament and to the Member States. The latter accountability relation hints at the most genuinely supranational feature in the accountability regimes for E.U. agencies, which is a specific horizontal accountability mode applied by the Member States. In the system of European administration, the federal entities operate completely differently than in the institutional setting of U.S.

276. *See*, *e.g.*, Damien Geradin, *The Development of European Regulatory Agencies: What the EU Should Learn from American Experience*, 11 COLUM. J. EUR. L. 1, 2 (2004-2005) (arguing that "the EU would benefit from the adoption of a European version of the APA"). *See also* Peter L. Strauss, *Rulemaking in the Ages of Globalization and Information: What America Can Learn from Europe, and Vice Versa*, 12 COLUM. J. EUR. L. 645 (2006) (comparing how the European Commission shapes statutes and regulations with American approaches to administrative rulemaking).

federalism. The Member States govern over a broad set of control mechanisms, including the work of their representatives in the E.U. agencies' management boards and expert committees, the day-to-day practice of European network administration, and political actions on the national level. With regard to future prospects, the article identified several fascinating issues. The new European Treaty of Lisbon of December 2007 provides for the constitutionalization of the E.U. agency regime. The reform treaty grants access to agency documents and judicial review against agency action. To that extent, it represents a remarkable unification of the currently very diverse accountability regimes for E.U. agencies. Moreover, with the emergence of global licensing cooperation between European agencies and global counterparts such as the U.S. Federal Aviation Administration and the U.S. Food and Drug Administration, there are novel and important accountability issues on the horizon.